UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, *ex rel*, YNKDY-2 and James Gordon STATE OF NEW YORK, ex rel, YNKDY-2, and James Gordon, STATE OF NEW JERSEY, *ex rel* YNKDY-2, and James Gordon Relator, v. Shiel Medical Laboratory; Shiel Holdings, LLC; Fresenius Medical Care; BIM Medical, Inc.; Jack Basch; Fresenius Medical Care Holdings, Inc.; Spectra Holdco, LLC; Does 3-10, Inclusive, et al., Defendants.	Civil Action: 16-CV-1090 FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730 (b)(2) FOURTH AMENDED COMPLAINT FOR VIOLATIONS OF FEDERAL FALSE CLAIMS ACT JURY TRIAL DEMANDED

1. Relator brings this action against defendants pursuant to the False Claims Act, 31 U.S.C. §3729 et. seq. ("FCA"), seeking treble damages and civil penalties.

2. Shiel Medical Laboratory was founded in 1962 and was purchased by Jack Basch, Michael Inzlicht, and Arthur Meisels in 1994. Its gross receivables and net revenue grew rapidly, to the point where the laboratory business was purchased by Fresenius Medical Care of North America (hereafter, "Fresenius") in 2013 for nearly a quarter of a billion dollars. In November of 2013, Shiel became BIM Medical, Inc. Its President Chief Executive Officer is Jack Basch.

3. Shiel performs laboratory testing which, when used appropriately, informs physicians and other health care providers of chemical and biochemical changes in a patient's body. When properly used, this information can be useful to the diagnosis and treatment of disease.

4. Since at least 1996, Shiel has knowingly submitted hundreds of millions of dollars in false claims to the Medicare and New York and New Jersey Medicaid programs for tests that were not reasonable and necessary or that were furnished pursuant to prohibited referrals that resulted from Shiel's improper financial relationships with physicians and with skilled nursing facilities, in violation of the physician self-referral prohibition, 42 U.S.C. § 1395nn (commonly known as the "Stark Law"), and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

5. As Defendants knew, Medicare only covers tests that are reasonable and necessary for the treatment or diagnosis of an individual patient's illness or injury, based on his or her medical condition. 42 U.S.C. § 1395y(a)(1)(A). The need for each test for each patient must be individually assessed and documented in the patient's medical chart. 42 C.F.R. §§ 410.32(a), (d)(2). Defendants nonetheless sought to, and did, cause many physicians to routinely order extensive and expensive laboratory tests merely to make more money.

6. Shiel also paid illegal kickbacks to physicians and nursing homes in the free advertising, computer and hardware purchases to facilitate the shift to electronic medical records, gifts, parties, and expensive meals. In addition, Shiel offered kickbacks in the form ofsubstantial discounts to nursing homes on their Medicare Part A lab tests in exchange for an exclusive contract to Shiel to do all the lab work for the nursing homes' Medicare Part B patients. Relator was responsible for negotiating these discounts and therefore had personal knowledge of these kickbacks for the last twenty years.

I. JURISDICTION, VENUE, PARTIES

7. This action arises under the FCA, as amended, 31 U.S.C. §§ 3729-33, and under common law theories of payment by mistake of fact and unjust enrichment. This Courthas jurisdiction over this action under 31 U.S.C. § 3730(a) and 28 U.S.C. §§ 1345 and 1367(a).

8. Venue is proper in this Eastern District of New York pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a).

9. This Court may exercise personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a) and because Defendant resides and transacts business in this District.

10. Relator YNKDY-2 is a California corporation whose principal, James Gordon, held a senior position within Shiel and who has direct and personal knowledge of the matters alleged herein. He does not have personal knowledge of claims processing as he was in sales. Shiel was a large company that was doing over $100 million in business by 2013 and had 500-600 employees. With only the rarest of exceptions, he did not have access to the actual claim submissions or (except for the endpoint of a claim rejection) any of the technical details of paper or electronic claim submissions beyond his role with the requisition data, discussed *infra*. This is true for all types of claims, whether they originated from tests run on patients in a skilled nursing facility or on outpatients visiting medical offices. Gordon also had no access to the medical records of any patient

for whom Shiel billed Medicare or Medicaid for laboratory tests. Before this suit was filed, James Gordon, Relator's principal and agent (collectively and individually referred to as "Relator") voluntarily and on his own initiative contacted federal law enforcement and submitted evidence of Defendants' wrongdoing.

11. Shiel Medical Laboratory was the assumed name of the co-defendant BIM Medical, Inc., a private corporation incorporated in the State of New York with its principal place of business in Brooklyn, New York, which sold its assets to co-defendant Fresenius Medical Care in 2013.

12. Defendant BIM Medical, Inc., continued to do business after the asset sale in theState of New York with its principal place of business in Brooklyn, New York. It was owned by Jack Basch, Michael Inzlicht, and Arthur Meisels, the same partners who owned it when it sold the assets of the Shiel Medical Laboratories business.

13. Defendant Fresenius Medical Care is a publicly traded corporation incorporatedin Germany with its principal place of business in Bad Homburg, Germany. Its principal headquarters in the United States is in Waltham, Massachusetts, from which it conducts a nationwide health care business which last year generated $15.8 billion in revenue.

14. Defendant Shiel Holdings, LLC is a private limited liability company registered in the State of Delaware with its principal place of business in Waltham, Massachusetts.

15. Defendant Jack Basch is an individual residing within the Eastern District of New York.

16. Defendant Fresenius Medical Care Holdings, Inc. was alleged as a Doe defendant in earlier iterations of this Complaint. However, Plaintiffs have discovered evidence which warrants naming Fresenius Medical Care Holdings, Inc. herein, or adding it as a co-defendant, for the following reasons:

(a) Defendant Fresenius Medical Care Holdings, Inc. is a holding company, which, through its subsidiaries, provides global healthcare services. In 2013, this Defendant acquired Shiel.

(b) On November 18, 2016, this Defendant received a subpoena under the False Claims Act from the United States Attorney for this Court.

(c) In the course of preparing to respond to the subpoena, Fresenius "identified falsifications and misrepresentations in documents submitted by a Shiel salesperson that relate[d] to the integrity of certain invoices submitted by Shiel for laboratory testing for patients in long term care facilities," Fresenius, Annual Report 2021 344 (2022).

(d) Fresenius terminated the employee and notified the United States Attorney of the termination (and the circumstances leading to the termination) on February 21, 2017; and

(e) Fresenius terminated the employee, but Fresenius understood that the terminated employee's conduct was expected to result in demands for Fresenius to refund overpayments and to pay related penalties under applicable laws, though the monetary value of such payment demands could not yet be reasonably estimated.

17. Defendant Spectra Holdco, LLC was alleged as a Doe defendant in earlier iterations of this Complaint. However, Plaintiffs have discovered evidence which warrants naming Spectra Holdco, LLC herein, or adding it as a co-defendant, for the following reasons:

(a) Spectra Holdco, LLC is a limited liability company, registered in the State of Delaware, which is related to Defendants Shiel Medical Laboratory and Fresenius Medical Care Holdings, Inc. and which appears to operate as a holding company in the Fresenius network;

(b) Spectra Holdco, LLC has the same address as Fresenius Medical Care North America, located in Waltham, Massachusetts;

(c) In an email correspondence on September 19, 2022, Fresenius counsel stated that it would be willing to accept service on behalf of the properly named defendants, "Spectra Holdco, Inc." and "Fresenius Medical Care Holdings, Inc."; and

(d) In a later email correspondence on September 22, 2022, Fresenius counsel clarified that the properly named defendants were "Spectra Holdco, LLC" and "Fresenius Medical Care Holdings, Inc." Relator accepted counsel's representation notwithstanding the fact that Phillip Hayden, Vice President of Finance and Barry Schwartz, Senior Director of Reimbursement, both had and used email addresses indicating their affiliation with Fresenius Medical Care North America (@fmc-na.com)

18. Each and every one of the remaining fictitiously named Doe Defendants is an individual or corporation which has submitted or caused the submission of false claims, acting in concertwith one or more of the other defendants.

19. Relator is informed and believes and based thereon alleges that each and everyone of the defendants has acted as the agent, director, or co-venturer of every other defendantto submit or cause the submission of false claims to the United States and to the States of NewYork and New Jersey.

II. LAW

A. The Federal False Claims Act

20. The FCA provides, in pertinent part, that a person who:

> (a) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]

> (b) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; . . .
>
> is liable to the United States Government for a civil penalty of notless than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount ofdamages which the Government sustains . . . .

31 U.S.C. § 3729(a)(1).[1]

21. For purposes of the FCA,

> **(1)** the terms "knowing" and "knowingly"—
>
> (A) mean that a person, with respect to information—
>
> (i) has actual knowledge of the information;
>
> (ii) acts in deliberate ignorance of the truth or falsity of the information; or
>
> (iii) acts in reckless disregard of the truth or falsity of the information; and
>
> (B) require no proof of specific intent to defraud[.] 31 U.S.C. § 3729(b)(1).

22. An overpayment is a payment by a federal entity to a provider or supplier inexcess of what was due and payable. An overpayment may include payment for non-covered items or services including services that are not reasonable and necessary in accordance with the Medicare rules. An overpayment may be received through an innocent billing error or through a mistake of the contractor. 42 U.S.C. Section 1320a -7k(d)(1) warns that "returning the overpayment . . . is an obligation (as defined in 3729(b)(3) of title 31 for purposes of section3729 of such title."

[1] The FCA was amended pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 ("FERA"), enacted May 20, 2009. Sections 3729(a)(1) of the prior statute applies to conduct that occurred before FERA was enacted, and Section 3729(a)(1)(A) of the revised statute applies to conduct after FERA was enacted. Section 3729(a)(1)(B) is applicable to all claims in this case by virtue of Section 4(f) of FERA.

23. As of May 24, 2010, the effective day of the legislation that established subsection 7k(d)(1), each day that a provider retains an overpayment, it is violating the FederalFalse Claims Act.

24. A refusal to calculate or estimate the amount of overpayment refunds owed isa separate violation of 31 U.S.C. §3729(b)(3) of the False Claims Act.

B. The Medicare and Medicaid Programs

1. The Medicare Program

25. In 1965, Congress enacted Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq*., known as the Medicare program. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. 42 U.S.C. §§ 426, 426-1. CMS administersthe Medicare program. At all times relevant to this complaint, CMS contracted with private contractors, referred to as "fiscal intermediaries," "carriers," and Medicare Administrative Contractors ("MACs"), to act as agents in reviewing and paying claims submitted by health care providers. 42 U.S.C. §§ 1395h, 1395u; 42 C.F.R. §§ 421.3, 421.100, 421.104. The Medicare program consists of four parts: A, B, C, and D. Defendants billed Medicare under Part B, which covers certain medical services, such as clinical laboratory test services,furnished by physicians and other providers and suppliers. 42 U.S.C. § 1395k(a)(2)(B).

26. To continue to participate in the Medicare program as an enrollee, clinicallaboratories, such as Shiel were required to submit a Medicare Enrollment Application.

27. Laboratories also complete Form CMS-855B to change information or to reactivate, revalidate and/or terminate Medicare enrollment.

28. Medicare regulations require providers and suppliers to certify that they meet, and will continue to meet, the requirements of the Medicare statute and regulations. 42 C.F.R. § 424.516(a)(1).

29. An authorized official must sign the "Certification Section" in Section 15 of Form CMS-855B, which "legally and financially binds [the] supplier to all of the laws,regulations, and program instructions of the Medicare program."

30. Relator is informed and believes and based thereon alleges that authorized. officials for Shiel Medical Laboratory and later Fresenius signed the certification statement inSection 15 of Form CMS-855B, indicating that they understood that the laboratory was required to comply with Medicare laws, regulations, and program instructions, which include,but are not limited to, the Stark Law and the Anti-Kickback Statute.

31. The National Provider Identifier ("NPI") is a standard and unique health. identifier for health care providers. All providers and practitioners must have an assigned NPI number prior to enrolling in Medicare.

32. To obtain Medicare and Medicaid reimbursement for certain outpatient items or and services, providers and suppliers submit a claim form known as the CMS 1500 form ("CMS1500") or its electronic equivalent known as the 837P form. The information the provider or supplier includes on a CMS 1500 or 837P form are certain five-digit codes, including Current Procedural Terminology Codes ("CPT codes") and Healthcare Common Procedure Coding System ("HCPCS") Level II codes, that identify the services rendered and for which reimbursement is sought, and the unique billing identification number of the"rendering provider" and the "referring provider or other source."

33. Beginning in 1996, laboratories submitting bills to Medicare were required to. ensure that the ordering physician had identified the specific medical condition which justified the laboratory test or tests. The medical condition was to be described using the International

Classification of Diseases, Edition 9 (ICD-9), which coded different disease states[2]. The ICD-9 code used to justify the laboratory test must be kept on file by the clinical laboratory.

34. Medicare Part A authorizes the payment of federal funds for hospitalization and post-hospitalization care. 42 U.S.C.§ 1395c-1395i-2(1992). Medicare Part B authorizes the payment of federal funds for medical and other health services, including without limitation physician services, supplies and services incident to physician services, labor tory services, outpatient therapy, diagnostic services, and radiology services. 42 U.S.C. § 1395(k), (i), (s).

35. For enrollees of Medicare and other federal insurance programs, Part A of the program provides coverage for up to 100 days for skilled therapy services provided toa beneficiary while inpatient in a SNF. For Medicare Part A patients, Medicare reimbursesthe SNF on a prospective payment system (PPS) with the prospective payments adjusted to take into consideration the patient's acuity and likely care needs. Payment for lab services under Part A are included in the SNF PPS rate.

36. Part B of the Program provides coverage for skilled therapy to beneficiaries who have either exhausted their Part A benefit or are not otherwise entitled to Part A coverage. Labservices for Medicare patients covered under Part B are either billed directly by the laboratoryproviding the services or, if the SNF provides the services itself (and is properly qualified underthe Clinical Laboratory Improvement Act) the SNF may directly bill Medicare for the services.In addition to the Medicare fee schedules for the tests, the laboratories may also bill for obtaining the specimen and for travel to the SNF patient.

[2] Beginning October1, 2015, CMS required that the new, ICD-10 codes be used instead.

37. Because a SNF which receives PPS reimbursement for Part A patients is being paid for the anticipated cost of lab services, the SNF is then financially liable for lab services those patients require.

38. Medicare requires that each request for payment or bill submitted for an item or service payable under Medicare Part B include the name and unique physician identification number for the referring physician. 42 U.S.C. § 1395l(q)(1).

39. From 2007 to the present, National Government Services (NGS) has been responsible for processing Medicare Part B claims in New York. As Defendants performed allof its tests at facilities in New York, it submitted all claims to NGS.

III. LOCAL COVERAGE DETERMINATIONS (LCDs)

40. The U.S. Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) promulgate federal regulations and National Coverage Determinations (NCDs) upon which Medicare Fiscal Intermediaries/carriers rely tomake coverage determinations for claims for medical services and items provided to beneficiaries. HHS adopts NCDs to exclude certain items and services from coverage on a national level that are not reasonable and necessary under HHS's interpretation of the Medicare Act. Federal regulations and NCDs are binding on all MACs nationwide. (42 U.S.C.1395ff(f)(1)(B).

41. In the absence of a NCD, Fiscal Intermediaries/Carriers, now Medicare Administrative Contractors (MACs) and their divisions such as the DMERCs, were authorizedto establish policies now known as (LMRPs) Local Coverage Determinations (LCDs).

42. When a service is not governed by a NCD, each Carrier could issue an LCD identifying indications and limitations of coverage and payment. *See* 42 U.S.C. 1395kk- 1(a)(4).

43. LCDs establish specific criteria for initial and continued coverage of a service and identify circumstances under which Medicare will deny coverage for a service as not reasonable and necessary. *See* 42 C.F.R. §400.202. The Social Security Act defines Local Coverage Determination as:

> (B) Definition of local coverage determination.
> For purposes of this section, the term "local coverage determination" means a determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary or carrier-wide basis under such parts, in accordance with section 1862(a)(1)(A). 42 U.S.C.
> §1395ff (f)(2)(B).

44. Each of MACs publishes and provides LCDs to the providers in its region.

45. Medicare does not pay for medical treatments or diagnostic services that are not reasonable and necessary. 42 U.S.C. §1395y(a)(1)(A), 42 CFR §411.15(k).

46. CMS publishes a Medicare Program Integrity Manual which instructs the MACs (Medicare Administrative Contrctors) that when determining whether a treatment is reasonable and necessary under §1395(y)(a)(1)(A), they may apply the so-called "reasonably feasible and medically appropriate, least costly" alternative policy. (Chapter 13.4.A, Rev. 71, April 9, 2004). Chapter 13 of the Medicare Program Integrity Manual provides the following detailed information regarding LCDs:

> 13.1.3 - Local Coverage Determinations (LCDs)
> (Rev. 165, Issued: 10-06-06, Effective: 09-11-06, Implementation: 10-26-06)
>
> Section 522 of the Benefits Improvement and Protection Act (BIPA) created the term "local coverage determination" (LCD). An LCD is a decision by a Medicare administrative contractor (MAC), fiscal intermediary or carrier whether to cover a particular service on a MAC-wide, intermediary wide or carrier-wide basis in accordance with Section 1862(a)(1)(A) of the Social Security Act (i.e., a determination as to whether the service is reasonable and necessary).
> . . .

2. The New York Medicaid Program

47. The New York State Medicaid Program is authorized by Title XIX of the Social Security Act. 42 U.S.C. §§ 1396 *et seq*. Medicaid is a joint federal-state program that provides healthcare benefits, including laboratory services coverage, for certain groups including the poorand disabled. The New York Medicaid program is required to implement a "State Plan" containing certain specified minimum criteria for coverage and payment of claims in order to qualify for federal funds for Medicaid expenditures. 42 U.S.C. § 1396a. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage, is basedon a state's per capita income compared to the national average. 42 U.S.C. § 1396d (b).

> Medicaid guidance, (e.g., the "New York Medicaid Provider Manual for Laboratory Services) is issued to give Medicaid providers the policies and procedures needed to properly bill and be appropriately paid for covered services provided to eligible New York Medicaid recipients. Physicians and laboratories certify in their state Medicaid provider enrollment forms that they will comply with all federal and state laws applicable to Medicaid. New York's "Medicaid Provider Enrollment Application" must be completed by any person or entity desiring to receive payment for services provided to Medicaid recipients. To be eligible to receive direct or indirect payments for services rendered to New York Medicaid Program recipients, a provider must certify that the provider understands "that false claims, statements, documents, or concealment of material facts may be prosecuted under applicable federal and state laws."

New York Provider Enrollment Application, Section VII, Certification,

48. The New York Medicaid Provider Laboratory Handbook warns that Medicaid does not pay for services unless they are medically necessary as evident from documentation in the enrollee's medical record. The Handbook also makes clear the warning that knowingly making a claim for inappropriate or unnecessary services is forbidden. Finally, with each claim,Shiel and Fresenius are required to certify that the laboratory services were furnished in accordance with

applicable federal and state laws and regulations, and that no material fact hasbeen omitted from the claim form.

49. Pursuant to New York's Electronic Claims Submission Agreement, all providers must abide by all Federal and State statutes, rules, regulations, and manuals governing the New York Medicaid program. The agreement also requires providers to certify that each claim is in compliance with all federal and state laws and the conditions on the claim form, including that "the services . . . were medically indicated and necessary to the health of this patient" and that the provider understands "that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws."

50. In addition, New York Codes, Rules and Regulations Title 18, Section 505.7 g(1) specifically requires that NY Medicaid (the NYS Medical Assistance program) "payment for laboratory services will be in an amount equal to the lower of: the amount specified in the MAfee schedule for laboratory services or the fee charged for laboratory services provided to the general public by the laboratory."18 CRR-NY 505.7 g (1). Therefore, any discounts that resultin payment lower than the MA fee schedule are not permitted.

51. Shiel offered nursing homes substantial discounts on their Medicare Part A lab tests, in exchange for an exclusive contract to Shiel for all Part B work.

52. The discounts offered were intended to induce and actually did induce the nursing homes to give Shiel exclusive contracts for all laboratory services to the homes' Part B patients.

53. The resultant discounts led to Medicare payments which were below the NYS MA fee schedule amount. New York Medicaid, instead of paying the fee schedule rate for these tests, should have been paid the lesser amount (the discounted Medicare rate.)

3. The New Jersey Medicaid Program

54. The New Jersey State Medicaid Program is authorized by Title XIX of the Social Security Act. 42 U.S.C. §§ 1396 *et seq*. Medicaid is a joint federal-state program that provides healthcare benefits, including laboratory services coverage, for certain groups including the poor and disabled. The New Jersey Medicaid program is required to implement a"State Plan" containing certain specified minimum criteria for coverage and payment of claimsin order to qualify for federal funds for Medicaid expenditures. 42 U.S.C. § 1396a. The federalportion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage, is based on a state's per capita income compared to the national average. 42 U.S.C. § 1396d (b).

55. Physicians and laboratories certify in their state Medicaid provider enrollment forms that they will comply with all federal and state laws applicable to Medicaid. New Jersey's "Medicaid Provider Enrollment Application" must be completed by any person or entity desiring to receive payment for services provided to Medicaid recipients.

4. Regulations Regarding Coverage for Laboratory Tests

56. Medicare and New York and New Jersey Medicaid regulations both make clear that laboratory tests must be ordered by the physician treating the patient for the treatment of a specific illness or injury, that laboratory test orders that are not individualizedtoo patient need (or for which the need is not documented in the patient chart) are not coveredservices, and that claims for such services must be denied.

a. Medicare Coverage for Laboratory Tests

57. Laboratory services must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), as set forth at 42 C.F.R. Part 493.

58. Medicare Part B pays for covered diagnostic laboratory tests that are furnished by a laboratory. 42 C.F.R. § 410.32(d)(v). "Clinical laboratory services involve the . . . examination of materials derived from the human body for the diagnosis, prevention, or treatment of a disease or assessment of a medical condition." Medicare Benefit Policy Manual ("MBPM"), (Pub. 100-02), Ch. 15, § 80.1, available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf (visited March 15, 2014).

59. Medicare Part B only covers services, including diagnostic laboratory services, which are reasonable and necessary for the diagnosis or treatment of an illness. *See* 42 U.S.C. § 1395y(a)(1)(A) ("[N]o payment may be made under [Medicare] part A or part B . . . for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning ofa malformed body member[.]")

60. Pursuant to 42 C.F.R. § 410.32(a), all diagnostic tests "must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the managementof the beneficiary's specific medical problem. Tests not ordered by the physician who is treatingthe beneficiary are not reasonable and necessary." The MPBM's "Requirements for Ordering and Following Orders for Diagnostic Tests" define an "order" as "a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary [T]he physician must clearly document, in the medical record his or her intent that the test be performed." MPBM, Ch. 15, Section 80.6.1.

61. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary. 42 C.F.R. § 410.32(a). Clinical laboratory services must be ordered and used promptly by the physician who is treating the beneficiary as described in 42 C.F.R. § 410.32(a). MPBM, Ch. 15, § 80.1.

62. To assess whether those services are reasonable and necessary and whether reimbursement is appropriate, Medicare requires proper and complete documentation of the services rendered to beneficiaries and prohibits payment "to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period. 42 U.S.C. § 1395l(e); *see also* 42 U.S.C. § 1395u(c)(2)(B)(i) ("The term 'clean claim' means a claim that has no defect or impropriety (including any lack of any required substantiating documentation)").

63. Medicare regulations expressly state that a laboratory's claim for a service will be denied if there is not sufficient documentation in the patient's medical record to establish that the service was reasonable and necessary. 42 C.F.R. § 410.32(d)(3)

64. CMS regulations further empower laboratories to request documentation from physicians regarding medical necessity:

> (iii) Medical necessity. The entity submitting the claim may request additional diagnostic and other medical information from the ordering physician or nonphysician practitioner to document that the services it bills are reasonable and necessary. 42 C.F.R. § 410.32(d)(3).

65. The Department of Health and Human Services, Office of Inspector General ("HHS-OIG") has published Compliance Program Guidance for Clinical Laboratories in the Federal Register. 63 Fed Reg. 45076 (Aug. 24, 1998), available at https://oig.hhs.gov/authorities/docs/cpglab.pdf. (Visited January 17, 2016.) Among other things, the HHS-OIG guidance clarifies that laboratory order forms should emphasize the need for a justification and assessment of each test ordered and that Medicare does not pay for tests for screening purposes:

66. Therefore, Medicare may deny payment for a test that the physician believes is appropriate, but which does not meet Medicare coverage criteria (e.g., done for screening purposes) or where documentation in the entire patient record, does not support that the tests were reasonable and necessary for a given patient.

. . .

> Requisition design: While HCFA [(CMS)] does not design or approve requisition forms, laboratories should construct the requisition form to capture the correct program information as required by Federal or private health care programs and to promote the conscious ordering of tests by physicians or other authorized individuals. The laboratory should construct the requisition formto ensure that the physician or other authorized individual has made an independent medical necessity decision with regard to each test the laboratory will bill. . . **The form should contain a statement indicating that Medicare generally does not cover routine screening tests.**

. . . .

b. New York Medicaid Coverage for Laboratory Tests

67. New York Medicaid also requires that testing be individualized to the medical needs of patients and must be medically necessary.

c. Self-Referral and Anti-Kickback Prohibitions

(1). The Stark Law

68. The federal physician self-referral prohibition, 42 U.S.C. § 1395nn (commonly known as the "Stark Law") prohibits an entity from submitting claims to Medicare for twelve categories of "designated health services" ("DHS"), including clinical laboratory services, if such services were referred to the entity by a physician with whom the entity had a financial relationship that did not fall within a statutory or regulatory exception. 42 U.S.C. §§ 1395nn; *see also* 42 C.F.R. §§ 411.351 *et seq*.

69. Compliance with the Stark Law is a condition of payment by the Medicare program. Medicare may not pay for any DHS provided in violation of the Stark Law. *See*42 U.S.C. §§ 1395nn(a)(1), (g)(1).

70. The regulations interpreting the Stark Law require that "[a]n entity that collects payment for a designated health service that was performed pursuant to a prohibited referral must refund all collected amounts on a timely basis" 42 C.F.R. § 411.353(d).

71. A "financial relationship" includes a "compensation arrangement," which means any arrangement involving any "remuneration" paid to a referring physician "directly orindirectly, overtly or covertly, in cash or in kind" by the entity furnishing the DHS. *See* 42 U.S.C. §§ 1395nn(h)(1)(A) and (h)(1)(B).

72. Effective October 1, 2008, "a physician is deemed to 'stand in the shoes' of his or her physician organization and have a direct compensation arrangement with an entity furnishing DHS if -- (A) The only intervening entity between the physician and the entity furnishing [DHS] is his or her physician organization; and (B) The physician has an ownershipor investment interest in the physician organization." 42 C.F.R. § 411.354(c)(1)(ii).

73. Under the Stark Law, an "entity is considered to be furnishing DHS if it . . . [is the] entity that has presented a claim to Medicare for the [DHS]." 42 C.F.R. § 411.351.

74. A "referral" includes "the request by a physician for, or ordering of, or thecertifying or recertifying of the need for, any [DHS] for which payment may be made underMedicare Part B." 42 C.F.R. § 411.351. Physicians who order laboratory tests or sign standing orders delegating their authority to order such tests to registered nurses or physicians' assistants within pre-established parameters are referring patients for laboratory testing.

75. The Stark Law and its interpretive regulations contain exceptions for certain compensation arrangements. The statute and regulations also exempt certain items from the

definition of "remuneration," including items "used solely to (I) collect, transport, process, or store specimens for the entity providing the item, device, or supply, or (II) order or communicate the result of tests or procedures for such entity." 42 U.S.C. § 1395nn(h)(1)(C)(ii); 42 C.F.R. § 411.351.

(2) The Anti-Kickback Statute

76. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions would result in goods and services being provided that are medically unnecessary, of poor quality, orpotentially harmful to patients. To protect the integrity of federal health care programs from these difficult-to-detect harms, Congress enacted a per se prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback gave rise to overutilizationor poor quality of care. The statute was first enacted in 1972, and was strengthened in 1977 and1987, to ensure that kickbacks masquerading as legitimate transactions did not evade its reach.*See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and ©; 42 U.S.C. § 1320a-7b, Medicare- Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142;Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

77. The Anti-Kickback Statute prohibits any person or entity from making or accepting payment, in cash or in kind, to induce or reward any person for referring,recommending or arranging for federally funded medical services, including services provided under the Medicare and Medicaid programs. In pertinent part, the statute provides:

> (b) Illegal remunerations . . .
>
> **(3)** whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person–

> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order or arrange for or recommendpurchasing, leasing or ordering any good, facility, service, or item forwhich payment may be made in whole or in part under a Federal healthcare program, shall be guilty of a felony and upon conviction thereof,shall be fined not more than $25,000 or imprisoned for not more thanfive years, or both.

42 U.S.C. § 1320a-7b.

78. Compliance with the Anti-Kickback Statute is a condition of payment by the Medicare program. 42 U.S.C. § 1320a-7(b)(7).

IV. DEFENDANTS' FRAUDULENT SCHEMES

79. Defendants knowingly submitted and caused to be submitted false claims to Medicare and New York and New Jersey Medicaid for non-covered laboratory testing and testing that was not reasonable and necessary. 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. §410.32(a); MBPM, Ch. 15, Section 80.6.1.

80. Defendants illegally paid skilled nursing facilities and physicians remuneration in the form of gifts, expensive entertainment, payment of expenses for advertising, payment of expenses for EMR licensing, phlebotomists, and office support staff.

81. Defendants also paid kickbacks to skilled nursing facilities by giving them substantial discounts of Medicare Part A lab work in exchange for exclusive agreements to send Shiel all of the SNFs' Part B business.

82. Since March 23, 2010, defendants have knowingly failed and refused to report and return overpayments in violation of 42 USC §1320a-7k(d). This requirement was establishedin 2010 and specifically make the failure to report and return overpayments enforceable under the False Claims Act [31 USC §3729(b)(3) and applies the same broad definitions of "knowing" and

"knowingly" as the FCA. [§1128J, as added March 23, 2010 by P.L. 111-148, Title VI,Subtitle E, §6402(a), 124 Stat. 753.)

A. Shiel and Fresenius Knowingly Submitted Claims to Medicare and Medicaid for Tests That Were Not Reasonable and Necessary by Falsely Submitting Diagnostic Codes

83. As a laboratory and Medicare supplier, Shiel, and then Fresenius had an obligation to submit claims to Medicare only for tests that were reasonableand necessary for the diagnosis or treatment of individual patients. Documentation of medicalnecessity is required before Medicare and Medicaid will pay for laboratory claims. With onlya few exceptions, the programs will not pay for routine checkups or screening tests, defined as "diagnostic procedures performed in the absence of signs or symptoms."

84. Shiel paid its account representatives modest salaries and supplemented those salaries with commissions the representatives could earn based upon the laboratory'srevenue earned on their accounts. This gave representatives a strong incentive to ensure that tests were reimbursed fully to maximize the company's revenue and thereby their individual commissions.

85. Shiel (and subsequently BIM and Fresenius) did not receive any reimbursement for any of the tests they performed unless the ICD-9 or later the ICD-10 code entered upon submission to Medicare was ` a of codes indicating the patient had a condition or symptoms such that the lab test was reasonably medically necessary, resulting in Medicare reimbursement. Therefore, many of the tests performed by Shiel on behalf of provider groups and nursing homes were initially rejected and not paid when Shiel submitted them for reimbursement because they either lacked ICD codes altogether, or lacked codes that would purportedly justify the tests Shiel was billing for. Shiel therefore started a campaign to make sure that all tests were coded

with a reimbursable code without regard to whether the provider ordering the test had authorized that diagnostic code for a particular patient.

86. Relator has seen multiple Explanations of Medicare Benefit forms (EOMBs) that show that claims were denied when initially submitted, but when ICD codes were later added, even without authorization from the physician who ordered a test, the claims were paid upon resubmission. In some cases, claims were resubmitted multiple times to ensure that all possible revenue was captured.

87. Representatives were instructed by Shiel to ensure that facilities added codes that would be reimbursable to their lab requisition forms. For example Realtor would try to ensure that for every nursing home facility he went to, he individually trained providers, the directors of nursing, assistant directors of nursing and all administrative staff to enter "common codes" from a list generated by Shiel upper level management, Tod Schild and Ann McGarrett.

88. This was necessary since physicians and skilled nursing facilities only infrequently inserted ICD-9 (nowICD-10) codes on their patients' laboratory requisition forms. The account representatives in a highly competitive market were reluctant to annoy providers or their office staff by assertively requiring them to include codes. An October 10, 2014 email from account representative Paul Tarantino to Tod Schild illustrates this point. Tarantino wrote:

> "Do we have a published list of payable icd9 codes pertaining to pre ops. The office mgr threatened to quit since the piles of codes are getting bigger. Has no time for this. That exercise will not work in Brooklyn. I know Quality and Lesco keep calling on them. I cannot afford to lose any more accts. Difficult to replace a good revenue acct. I am going today at 4 to try to help with a solution. If we have a tool that can help will be great."

89. Because of the burdens on medical office staff and less demanding companies that were waiting in the wings, the Shiel sales staff were faced with a dilemma. Shiel would not get paid, and the account representatives would not earn commissions unless Shiel itself inserted the

codes. Yet requiring those codes would drive their customers into the arms of the competition.

90. Shiel taught its account representatives to insert codes themselves, with no knowledge of whether the codes were proper. As commissioned salespeople, their only concern was whether the codes would get Medicare to pay for the tests. To help ensure that only reimbursable codes were used, a cheat sheet was created by Tod Schild and Ann McGarrett (SVP Director of Sales and Marketing and Manager of Marketing respectively) with input from Gitty Kohn, VP of Billing and Contracting and Compliance Manager. This "common codes" sheet was a list of diagnostic codes that would cause Medicare to pay for Shiel's lab tests reimburse. Relator and other sales representatives like him were told to ensure that requisition forms had codes from this list added before they submitted them to Gitty Kohn and Toby Goldstein-Friedman, Senior Billing Manager for submission to Medicare. Jack Basch and other Shiel executives exhorted their account representatives by telling them, "You've got to put down an ICD-9," and, "You've just got to do it."

91. The pressure to make sure reimbursable codes were added was so intense that in 2009 Steve Morea, who was one of the reps who added the most codes, enlisted a phlebotomist at Shiel's Rockville Centre Patient Service Center. The phlebotomist, Daysi, was given a list of ICD9 codes and told to input a reimbursable code from the list when a test was not covered. When this was brought to the attention of Gitty Kohn, she made a show of bringing the issue to Moshe Kraus and Jack Basch. Ann McGarrett, who was responsible for a number of doctors referring to Rockville Centre, wrote to Gitty concerned that this was being brought to Basch and Kraus and expressing concern over the legality of Daysi's actions. Gitty responded to McGarrett's email, writing that if Daysi "is taking it upon herself to [add reimbursable codes], she needs to be told to stop it immediately". Despite this written show of attempting to remain in compliance, nothing was done. Daysi continued to work at the Rockville Centre PSC and continued to input codes.

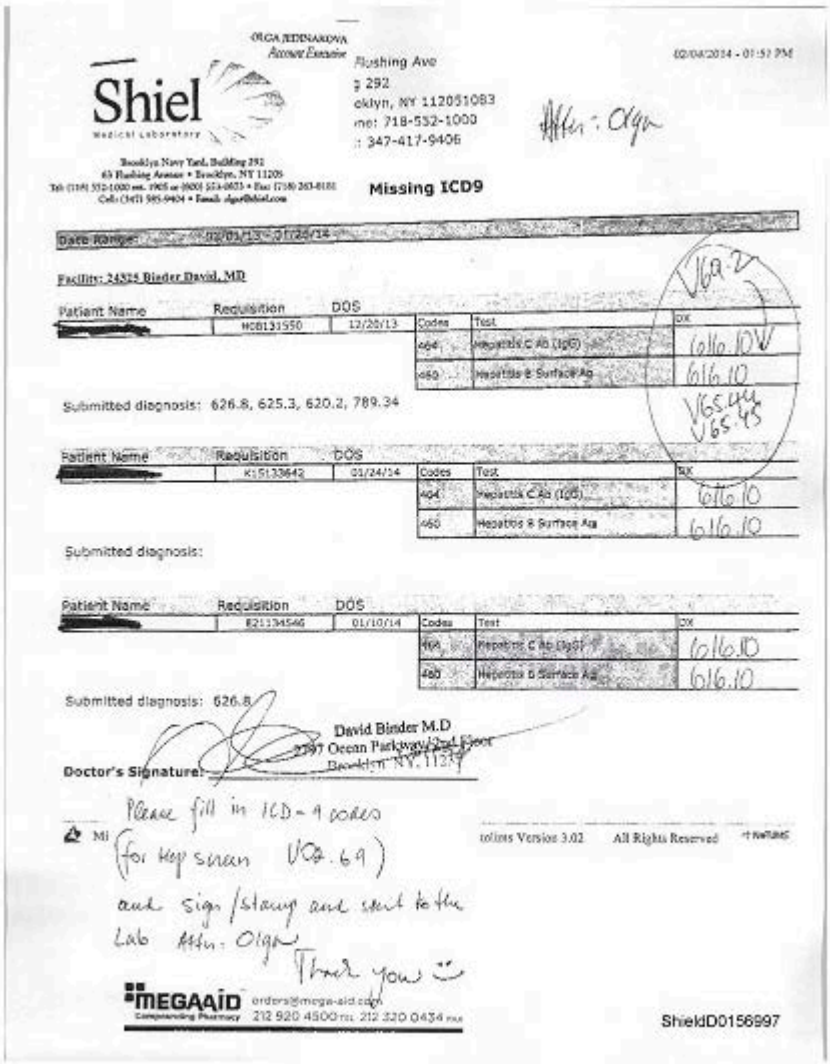
92. Jack Basch was particularly involved in ensuring codes were added by account representatives. Relator was pressured by Basch almost daily, whenever he saw him, to make sure he was adding codes. Basch would ask Relator, "Where are my codes? I'm choking here", which Relator understood to mean that Basch needed money. Basch also directly begged Relator to do the codes, stating that he "Need[s] money—do the codes. There's no money coming in, please".

93. Shiel office workers routinely received printed version of the "missing diagnosis" sheets for laboratory test requisitions which were unpaid because ICD-9 codes were missing, or because the codes which had been selected did not result in payment. These requisitions were either put in the account representatives' inboxes, left at billing office desks, or in some cases, delivered to the account representatives.

94. Relator has a number of these "Missing ICD9" sheets which cover the period between March 2013 and December 2015. These sheets contain over a hundred examples of "missing" ICD9 codes that have been added in by hand. These codes were all pulled from lists of reimbursable codes that the account representatives were given. Relator also has examples of around 1000 codes that were written in by Steve Morea, one of the reps who historically had the highest rate of adding in reimbursable codes. These codes were also written in on "Missing ICD9" sheets and cover the period between November 2007 through April 2009 and May 2014 through September 2015. Because these sheets contain patient names, to comply with HIPAA, Relator will provide these to Defendants pursuant to a HIPAA- qualified protective order and/or will seek leave from the court to have them filed under seal.

95. Shiel and Basch (and later BIM) wanted billable ICD9/10 codes inserted whether the doctors had authorized them or not. But these defendants demanded that its sales staff be subtle. A solution from one Shiel employee created a firestorm when, on February 4, 2014 she

sent the following, instructing a doctor to use an altogether different code, even if it was incorrect, so long as Shiel got paid.



Shiel
medical laboratory

Missing ICD9

Facility: 24325 Binder David, MD

Patient Name	Requisition	DOS	Codes	Test	Dx
[redacted]	H08131550	12/26/13	464	Hepatitis C Ab (IgG)	616.10
			460	Hepatitis B Surface Ag	616.10

Submitted diagnosis: 626.8, 625.3, 620.2, 789.34

Patient Name	Requisition	DOS	Codes	Test	Dx
[redacted]	K15133642	01/24/14	464	Hepatitis C Ab (IgG)	616.10
			460	Hepatitis B Surface Ag	616.10

Submitted diagnosis:

Patient Name	Requisition	DOS	Codes	Test	Dx
[redacted]	B211345465	01/10/14	464	Hepatitis C Ab (IgG)	616.10
			460	Hepatitis B Surface Ag	616.10

Submitted diagnosis: 626.8

David Binder M.D
2307 Ocean Parkway 2nd Floor
Brooklyn, NY 11235

Doctor's Signature:

Please fill in ICD-9 codes (for Hep screen V04.89) and sign/stamp and send to the Lab Attn: Olga Thank you

MEGAAID Compounding Pharmacy orders@mega-aid.com 212 920 4500 ph 212 320 0434 fax

ShieldD0156997

96. "Compliance" Chief Gitty Kohn's first response? "She needs to understand that you cannot put that in writing on something that will be a legal document for years. . .United [the insurer in this case] has its own list of payable codes for Hepatitis and you need to refer to those. You cannot use the Medicare list for United claims." Although this is

"merely" evidence of private insurance fraud rather than Medicare fraud, this speaks volumes about Shiel's approach to the problem.

97. The unremitting pressure Shiel placed on the sales reps invited, and nearly required them to commit fraud. Payers, including New York Medicaid, commonly require that claims be submitted within 90 days of a service. On March 14, 2012, Basch's right-hand man, Moshe Kraus wrote to Schild: "These reps didn't even request their missing ICD9 codes since January for the insurances that only have a 90-day filing period". This meant that the reps now had two weeks in which to either obtain legitimate ICD9 codes from their doctors, or to simply create them. So intent was Kraus in forcing the sales staff to write in codes themselves that he used the specter of Jack Basch's anger to bully them – all with Basch's knowledge. On March 23, 2010 Kraus warned Anne McGarrett, "[Y]ou have over 43,000 in missing icd9 codes and time is running out fast . .." copying Basch on the email so that Basch could see and assist with the bullying.

98. The problem was so widespread that Shiel continued to submit Medicare claims for unauthorized services, long after the Fresenius/Spectra purchase. Here is just a sample of both inpatient (SNF) and outpatient claims for Medicare patients. (For five of the patients the payer was not specified but is presumptively Medicare based on the patients' quite advanced ages:

REQUISITION SLIPS WITH NO AUTHORIZATION

Requisition Number	Order or Collection Date	Payer(s)
LE542136658	08/11/2015	Medicare
LE65072396	08/17/2015	"
LE65072387	08/17/2015	"
LE65072382	08/17/2015	"
LE6507239LW19574	08/17/2015	"
LE65072384	08/17/2015	"
LE65072383	08/17/2015	"
I1213729	08/11/2015	"
G29152691	08/11/2015	"
LE25000005088	03/09/2016	"
Z23150413	03/09/2016	" (pt. 90 y/o)
B29160202	03/09/2016	" (pt. 84 y/o)
B29160333	03/09/2016	" (pt. 75 y/o)

L1621162	Unknown	Medicare / Medicaid
LC726008346	03/08/2016	Medicare
Z31152947	01/18/2016	" (pt. 91 y/o)
LW1962005294	01/28/2016	Medicare / Medicaid
LW1957002536	01/28/2016	Medicare
Z24151383	01/27/2016	"
LC317029616	02/05/2016	"
L1485576	01/30/2016	"
LW1418005957	12/28/2015	"
LW1912002647	02/05/2016	"
L1598913	01/18/2016	" (pt. 89 y/o)
LW1397005018	01/28/2016	"

99. With nursing homes, as with outpatients, Shiel wanted the providers to use codes that would get Medicare to pay the lab charges. On April 24, 2012 Vice President of Billing and Compliance, Gitty Kohn wrote "We are getting lots of well visit diagnosis codes on the requisition forms from the nursing homes. Medicare does not cover under a routine well visit code. Can you please speak to the homes especially Cliffside, Midway and Silvercrest Center. ¶ They should not use V72.9 (Midway), V07.9 (silvercrest) [sic] or any other exam code starting with V. This just causes the claims to deny and be put on hold."

100. Shiel representatives who had nursing home accounts also routinely inserted codes to justify reimbursement even when newly admitted patients were receiving "baseline"tests which Medicare does not pay for. The patients also had regularly scheduled routine testswhich, in the absence of signs, symptoms, or diagnoses, are also not reimbursable. Nursing homes would input the codes that were appropriate based on the patients' charts; because these were not reimbursable, Shiel employees were told the ensure that reimbursable codes from the approved "common codes" list were inputted prior to submission to Medicare. The account representatives typically used the following ICD-9 codes:

Code	Meaning
V58.61	Long term use of anticoagulant
V58.69	Long term use of medication
244.9	Unspecified acquired hypothyroidism
250.00	Diabtes melitus without mention of complications
780.79	Malaise and fatigue
599.0	Urinary tract infection
790.6	Other abnormal blood chemistry
V76.44	Screening for malignant neoplasm of the prostate
268.9	Vitamin D deficiency
285.9	Anemia unspecified
272.4	Unspecified hyperlipidemia
790.99	Other non-specific findings of examination of blood
428.0	Congestive heart failure, unspecified
280.9	Iron deficiency, anemia
788.41	Urinary frequency
427.31	Atrial fibrillation
733.00	Osteoporosis unspecified
245.0	Acute thyroiditis

101. A similar set of common codes existed for the ICD-10 codes.

102. On January 7, 2015, a full year after the Fresenius/Spectra acquisition, Joel Basch was coaching Luis Peńa, a Shiel technical manager on which cheat sheet was the most comprehensive and should be uniformly rolled out to all Shiel-contracted SNFs.

103. Shiel/BIM deliberately set up and maintained its software so that the account representatives would be bombarded by multiple "missing code diagnosis" forms even when many months, or even years went by. Shiel tracked the "missing code" forms by representative as a further means of pressuring them and refused requests to remove items from this list. In June of 2015, long after Fresenius / Spectra had purchased Shiel Senior Account Executive Brian Gluck emailed Gitty Kohn, the Vice President of Billing and Contracting and Compliance, asking that outdated "missing diagnosis" forms be removed from the system. Gluck's request was supported by Tod Schild, Senior Vice President of Sales and Marketing. Kohn responded that she was certain that Phil Hayden of Fresenius/Spectra would not want it removed.

104. All the account representatives were pressured to ensure that codes were added in order to ensure reimbursement. Steven Morea, David Needleman, Sal Prifitera, Teddy Kohn, Etya Esposito and George Inzlicht as well as Relator himself, were among the representatives who completed the most requisition forms by inserting diagnosis codes that had not been given them by the doctors who ordered the tests. When filling out these requisition forms, reps would simply write the reimbursable codes from the "cheat sheet" onto the form in their own handwriting. Some reps, including Etya Esposito and Neil Wyman, also forged doctor signatures on the forms. All of these reps worked off of the same "cheat sheet" of common codes that was disseminated by Tod Schild.

105. Jack Basch, both personally and through his top executives Joshua Basch and Moshe Kraus, maintained relentless pressure on the account representatives. On December 16, 2009, Joshua Basch, wrote Relator, citing statistics about missing codes and stating, "Jack want to know what's up?" On November 17, 2011, Kraus wrote to Schild, "I think it's [sic] embarrassing to Jack that he has to call to get the missing codes. Schild took the hint. On April 26, 2012, in the

midst of another effort to demand codes Tod Schild sent an email emphasizing that these were "Jacks [sic] orders".

106. The pressure campaign continued after the Fresenius/Spectra acquisition. In January of 2016 Senior Billing Manager Toby Goldstein-Friedman called Gordon and said calls were being made to Gordon and others pursuant to a request from Jack Basch to get the sales representatives to "do the codes" because "we need the money."

107. The pressure was felt and responded to. For example, in the two-week period of September 4-18, 2014, the following account representatives turned in diagnostic codes that were missing from requisitions:

Representative	Number of Code Sheets Turned in, Ostensibly Obtained from Ordering Providers
Sal Prifitera	22,568
Steve Morea	16,370
David Needleman	14,808
Frank May	4,881
Norman Riegel	3,953
Paul Tarantino	2,609
Cormac Barrett	2,000
Teddy Cohen	1,878

108. There is no possibility that a representative could actually contact providers about thousands of individual patients and get this amount of information. And it was clear to management how this was being achieved. On October 11, 2013 Kohn, as V.P. of Billing and Compliance informed Senior VP Tod Schild and COO Moshe Kraus that Account Representative Christine Thorp returned requisition sheets, none of which were signed by the doctor or staff,

merely stating "by phone", with no indication of who Thorp spoke to, or the time or date. Kohn further reported that Account Representative Nicholas Halper turned in "a large stack of codes". Kohn reported: "There is no signature or stamp for the sheets. Most of the form [sic] just has a code on the top of the page and a large arrow down the rest of the sheet." Although Kohn said she would not enter them into the system, no steps were taken to discipline either rep. The pressure also resulted in outright forgeries.

109. This was not the first time account representative Brian Gluck had succumbed to this pressure. On numerous occasions from the summer of 2015 to mid-October of 2016, Relator observed Gluck pick up the missing diagnosis forms, take them to a second-floor sales office or conference room, and fill out the forms and sign them himself. He observed Gluck turn in the now-completed forms for processing, often within hours of having picked up the missing diagnosis forms and without ever leaving the building. For example, on March 28, 2016, Gluck forged the signature of Lim Tse, M.D., and the signature of an unknown provider from Prospect Hills Medical Care to ICD10 forms. On that same day Gluck turned in forms supposedly signed by Harry Berkowitz, M.D., an unknown physician from Broadway Medical, Melinda Mann, M.D., and Michael Josovitz, M.D. Each of the four providers have very similar signatures, the same ink color, and very similar handwriting for the codes inserted.

110. Fresenius/Spectra was aware of all of this. Kohn told Relator and Toby Goldstein-Friedman that Hayden, Schwartz, and the Fresenius compliance director Peter Connelly knew about the fake codes and discussed it among themselves. In November of 2016 Brian Gluck reported that that Kohn had told him that Phil Hayden knew about the fake codes problem.

111. Only after the Justice Department had issued a Civil Investigative Demand, indicating that it was investigating False Claims Act charges surrounding the fake code insertion, did Fresenius, in January of 2017. issue a new policy on Obtaining and Assigning Diagnostic

Codes that said "Only a physician or other authorized person may render a diagnosis for a patient. If the laboratory requires a diagnosis code for billing purposes, it must be received directly from the ordering physician, an authorized designee, or a reviewing pathologist. Codes received from the ordering physician or authorized persons must be documented in writing on the test request form or another documentation source request form."

112. On February 8, 2017. while Relator was still an employee, he was interviewed by Fresenius and by outside counsel from Hogan Lovells. During this interview Relator informed Fresenius about all of the fraudulent conduct he had observed and had felt pressured to engage in. This included the insertion of reimbursable codes onto requisitions forms despite the fact that these codes were not supported by the patients' charts or the actual physician orders. During this interview, Relator also disclosed Shiel's practices in providing expensive EMR systems and maintenance fees to doctors with high volume accounts as an inducement to continue using Shiel as their lab. He also disclosed the discounts Shiel offered to nursing homes on their Medicare Part A work in exchange for exclusivity on Medicare Part B billing. Finally, he disclosed Shiel's practice of providing doctors and practices with high volume accounts expensive gifts of wine and tickets to the theater and sporting events. During the interview he also told Fresenius about the parties that were thrown for these doctors/practices. He explained that all of these practices were done to induce these nursing homes, doctors and practices to continue to give their lab business to Shiel and subsequently Fresenius.

113. Since Relator had a great many nursing home accounts, he would go through the list of reimbursable codes provided and select ones that would seem appropriate for nursing home patients, such as fever, fatigue or malaise with no knowledge of whether or not these codes were actually warranted given the patient's condition. The focus of all account reps was only to get the codes paid.

114. In the fall of 2014, Shiel and Fresenius helped introduce Lab Care software which its nursing home accounts would use to order laboratory tests. The software required the nursing homes to enter a diagnostic code for the order to be processed.

115. However, this did little or nothing to meet Medicare's requirement that orders include ICD-9 codes reflecting the medical condition which made the test necessary, and defendants' own chief compliance officer Gitty Kohn acknowledges that at least half of the tests are orderedor billed with improper diagnostic coding.

116. There are two reasons for this. First, the software-facilitated coding prompt does not require that the nursing home enter the correct code that demonstrates the medical necessity of the test. It does not even require that the nursing home enter a code which, although inaccurate, would nonetheless trick Medicare into paying for the test. Entering any diagnosticcode at all will cause the test requisition to process.

117. Second, defendant Shiel, via their executive staff, Tod Schild, Ann McGarrett and Gitty Kohn prepared "cheat sheets" similar to the sheets provided to their own account reps, that listed the diagnostic codes which would trigger Medicare payment even if they had nothing to do with the patients' condition. Account representatives first working for Shiel / BIM and then Fresenius / Spectra, trained nursing home employees to use the "cheat sheets" to enter diagnostic codeswhich would trick Medicare into paying for the laboratory tests whether or not there was any genuine evidence that the tests were medically necessary. They were joined in this by Moshe Kraus, Shiel's Chief Operating Officer, who reported directly to Jack Basch.

118. The falsification of ICD-9 and ICD-10 codes was known by Fresenius Laboratories' Chief Operating Officer and the vice-president of Billing and Contracting.

119. Phil Hayden, VP of Finance for Defendants Spectra and Fresenius was aware of Shiel's practices regarding the addition of reimbursable codes that were not warranted based on the patients' charts. He continued to facilitate this practice after Fresenius bought Shiel.

120. From January-June 2014, the majority of the sales reps slowed down adding codes and submitting modified requisition slips. Jack Basch told Gordon he needed to continue adding diagnostic codes, but cautioned him, "If you get caught, you're on your own." At this time, Relator completely stopped submitting reimbursable codes that were not supported by the patients' charts. In June 2014, Gitty Kohn took Relator aside and told him that Phil Hayden and Barry Schwartz, Spectra Director of Reimbursement were aware that sales reps had been entering reimbursable diagnosis codes on requisition slips where codes were missing or otherwise non-reimbursable. Hayden and Schwartz were concerned because revenue had gone down so drastically after Fresenius' purchase. Kohn told Relator that he had to start "doing it again" as things are "desperate" and that if Relator continues to refuse to add codes, Jack Basch would be forced to find someone else to do them. After this conversation, Basch met with Relator and offered him a significant sum of money paid out over 3 years to continue to add reimbursable codes. Based on this very strong incentive and his own financial need, Relator recommenced adding and resubmitting reimbursable codes as Basch required.

121. Basch retained his authority after Fresenius purchased Shiel and continued to pressure and exhort Relator and the other account representatives to add reimbursable codes until 2016.

B. Shiel and Fresenius Knowingly Submitted Claims to Medicare and Medicaid for Tests That Were Not Reasonable and Necessary by Adding Orders for Expensive and Unnecessary Tests

122. In 2014, after Fresenius acquired Shiel, a sales contest was held which offered the most successful sales representative a thirty percent commission on accounts generating over $50,000 in monthly billings. The contest winner, Sal Prifitera, boasted that he had done this by automatically adding orders for expensive services such as Vitamin D assays (CPT Code 82306 and Oxidized LDL tests. (CPT Code 83516.)[3]

123. This was hardly the first time Prifitera had done this. In a December 9, 2004 email, Prifitera was singled out for praise by then vice president of sales Todd Schild for gettinga medical practice to include ***routine*** Oxidized LDL tests on the chemistry panels it ordered. Schild pointed out that by doing this Prifitera had **doubled** Shiel's sales to this medical group,to $40,000 per month.

124. Schild also stressed in an email to Shiel account representatives in 2009 the vital importance of pushing Vitamin D testing on doctors during sales calls. He specifically stated that pushing Vitamin D testing is a opportunity to "significantly increase your account revenue".

125. The expensive oxidized LDL tests are governed by Medicare'sgeneral requirement that routine screening tests are not reimbursable.

126. In New York, Medicare reimbursements for Vitamin D assays are governed by Local Coverage Determination L29510 promulgated by the Medicare contractor, NGS. The LCD became effective September 1, 2009, and ruled that routine screening tests for Vitamin D

[3] Vitamin D assays are indicated for patients with any of the following conditions: chronic kidney disease State III or greater; osteoporosis osteomalacia; osteopenia; hypocalcemia; hypercalcemia; hypoparathyroidismk; hyperparathyroidism; or rickets. The assay test is also indicated to monitor the effectiveness of Vitamin D replacement therapy in patients with documented Vitamin D deficiency.

insufficiency are not reimbursable, and the assay is only indicated for patients who have been diagnosed with a few very specific diseases.[3] Testing without one of these specific diagnoses may not properly be billed to Medicare.

C. **Defendants Gave Financial Inducements to Physicians in Exchange for Referrals in Violation of the Stark Law and Anti-Kickback Statute**.

"Your company was so generous with the EMR and the equipment!"
Ali Aboufares, M.D., to Shiel rep Juan Martinez, June 7, 2011

127. Defendants have used a variety of means to provide financial inducements to doctors and nursing homes to encourage and reward referring their patients to Shiel.

128. Physicians are now required to switch their practices to electronic medical records (EMRs). Shiel pays the initial set up costs and the monthly licensing fee of hundreds of dollars per month for cloud-based EMR services. Relator is informed and believes and based thereon alleges that thesemonthly payments are made on behalf of approximately one hundred or more physicians who are customers of Shiel account representative Sal Prifitera.

129. Specifically, over 70 providers and provider groups and around 29 separate nursing homes received significant investments in the form of initial set up and installation costs and monthly maintenance costs from Shiel and subsequently BIM and Fresenius. Shiel, and subsequently BIM and Fresenius also provided many of these practices and providers with additional equipment such as computers, monitors, and tablets, and LabCare software interfaces. The tablets were not locked and therefore were not used solely for portable EMR purposes. Instead, providers would request tablets and then give them to their children or take them for personal use. For example, Relator had a conversation with a sales representative, Juan Martinez, wherein Martinez told him that the tablets were just out on providers' desks and being used for general, non-lab related purposes. The following physicians and practices are just a partial list of

those that received computers or tablets that were completely unrestricted and could be used for anything – not just laboratory-related information:

Poughkeepsie Medical Group – 5 computers;

Kevin Jovanovic, M.D. – 3 computers

Stat Medical 3 computers

SAssociated OB/GYN 2 computers

Dzanic Cemalovic Naida and Alan Ditchek, M.D., 1 computer and 1 printer

Allied Physicians, Cesar B. Holgado, M.D., Jessica Allan, M.D., Edward Ezrick, M.D., and HealthSure Medical Services each received one computer.

130. The highest value EMR set ups cost tens of thousands of dollars, with some set ups costing as much as $30,000. A certain subset of practices and providers received these high value EMR systems, the least expensive of which cost $5000 for software and installation in addition to the annual maintenance fees in the thousands of dollars and the tablets and other equipment provided. The practices that received these systems were also the practices that generated the most revenue for Shiel.

131. An account set up form was used to establish new accounts when a medical practice registered with Shiel. This form was also used to request approvals of the EMR set ups and annual fees. The last page of this form includes the estimated monthly value of the lab billings the practice was expected to generate. Approvals of EMR payouts depended heavily on this information.

132. The push to ensure that EMRs were only provided to practices with a high estimated volume of tests came from top level management at Shiel and subsequently Fresenius. Moshe Kraus, General Manager of Shiel, who became COO after Fresenius purchased Shiel, was in charge of EMR approvals. He would explicitly ask how much money the practice or

nursing home was generating before he would agree to provide the EMR software and maintenance fees. For example, on one occasion, when asked to approve a $4635 EMR payment for Farmingville Family Medicine, the first question Kraus asked was "What is the estimated monthly volume [in lab billing generated by the practice]. When he was told that it was $15,000 per month, the EMR was immediately approved. Similarly, when Kraus was approached about Rosh Maternal Fetal Medicine, on September 18, 2009, he wrote "I would like to see how that changes the profitability of the account before investing more money."

133. Tod Schild, SVP and Director of Sales and Marketing also explicitly conditioned EMR payments on estimate volume of lab tests. As early as June 23, 2010, he emailed his team that a doctor must be generating at least $3000 in monthly billing in order to be eligible for an EMR to be provided to that office. On June 29, 2010, Schild wrote that the $3000 requirement had been reviewed and that Shiel had decided it would not support EMR payments unless each physician in a practice was generating at least $5,000 per month in billing for Shiel.

134. This directive was echoed by Andy Khemraj, the IT director, who sent out an email that for Shiel to pay for specific EMR vendors, ADS and doctor.com, a doctor or practice would have to generate at least $6000 a month for a single doctor practice and $3000 additional revenue in lab billing for each additional doctor in the practice.

135. Sal Prifitera, Client Systems Director and VP of Business Development/IT, and the person in charge of the EMR program, also specifically conditioned provision of EMRs on volume of billing. When telling Dr. Menitove of Rockland Pulmonary that Shiel could help pay for the cost of an EMR, On February 3, 2009, Prifitera expressly conditioned this offer on a "greater commitment" from the doctor. Prifitera's email reporting this was sent to Jack Basch on February 5, 2009.

136. Shiel executive Ann McGarrett told Relator that Jack Basch "absolutely" turned a blind eye to these illegal dealings, because "Jack didn't give a shit, 'cause Jack was like, 'I want to be at this number, and then I want to sell.'"

137. Another knowledgeable account representative, Juan Martinez, told Relator there was an "arrangement" between one of the EMR vendors, MacPractice, and Prifitera. Martinez summed up the scheme, saying" MacPractice sends a rep in, quotes the MD $50,000 and says he has someone who will give him the deal for free so long as that person gets all the lab business."

138. Physicians benefiting from Shiel's generosity included Howard Hertz, with a $5,500 subsidy for installation and setup and $3,700 in annual vendor payments (2011-2014); Zev Brandel, M.D., with a $2,500 subsidy for EMR installation and set-up, and $4,500 in annual vendor service payments (2011-2015; and Alan Ditchek, M.D., who received a $2,500 subsidy for EMR installation and set-up and $3,300 in annual vendor service payments in 2012.,

139. After Fresenius purchased Shiel, this practice continued. In May 2014, Moshe Kraus was asked to approve an EMR which included a choice of either a $2500 vendor fee or a $5500 vendor fee. Because the doctor was only generating a relatively small amount of monthly lab billing, Kraus approved the lower cost vendor. EMR payments after the purchase included Boropark OBGYN ($13,500 installation and set-up and $1,610 in annual vendor service payments; Schulman Medical Associates, $3,000 for installation and setup, and $5,610 in annual vendor service payments, Alan Maslova, M.D., a $3,500 setup and $5,000 in annual vendor service payments, and Yosav Morad, M.D., a $3,500 charge for set-up and installation and $3,600 in annual vendor service payments. Fresenius/Spectra certainly wanted to keep Dr. Morad happy since he generated $130,000 per year in laboratory billing and had consistently done so since signing on with Shiel on August 4, 2010 after a conversation with Sal Prifitera, whom Schild had described as our "EHR specialty rep." in a May 26, 2010 email.

140. In 2015, a $10,000 initial set up fee and a monthly maintenance fee was approved for Dr. Hertz. Dr. Hertz's practice had a projected monthly volume of $45,000, and his practice generated over $202,000 in Medicare billings alone over the period between 2012-2015. All accounts approved in 2015 had a minimum of $5000 a month in revenue to Shiel/Fresenius.

141. Between 2009 and 2015, Shiel subsidized EMR purchases for at least 90 medical practice, nursing homes, and individual physicians, which in combination generated over $16,000,000 per year in revenue for Shiel. Relator is aware of and if necessary will name in public pleadings the many other physicians and medical groups that enjoyed similar benefits under these arrangements.

142. The medical practices receiving EMR payoffs 2009-2014 that were the most lucrative for Shiel/BIM (and later for Fresenius/Spectra) were City MD, Manhattan Hematology and Oncology, BIMAssociated OBGYN, Zev Brandel,M.D., Howard Hertz, M.D., Boropark OBGYN, Jamie Kane, M.D., Laura Kuperman, M.D., Victory Internal Medicine, Kim and Kim, and Maya Medical.

143. The skilled nursing facilities receiving EMR payoffs 2009-2014 that were the most lucrative for Shiel (and later for Fresenius/Spectra) were New Vanderbilt, Glen Cove, Palm Gardens, Fulton Commons, Grandell, Marquis Care Center, Excel at Woodbury, New York State Veterans' Home, and Bridgeview.

144. Relator is informed and believes and based thereon alleges that Shiel allowed itself to be overcharged by another EMR company, ELLKAY LLC, by a factor of approximately 400%, using some or all of the nearly one million dollars in funds generated by the overcharge to induce physician referrals. Shiel recently authorized one account representative to spend thousands of dollars for a party hosted by a physician, Amir Rabaddi, who gave business to Shiel.

145. Shiel also provides financial inducements to physicians by placingphlebotomists and other personnel in doctors' offices without charge, or by paying doctors' ownemployees to draw blood samples. For example, a Shiel employee who is an assistant to sales representative Brian Gluck actually reports to work at a Boro Park, New York OB GYN practicewhere she performs office functions which directly support the doctors. To camouflage the fact that providing in-house phlebotomy services is of great financial benefit to the doctor or medical group, Shiel would often rent space in the medical office building. Although federal law required that such "patient service centers" or PSCs be open to the public, Shiel went to great lengths not to advertise or even publicize the existence of such centers, so they could remain the private domains of Shiel's favored doctors. Jack Basch was fully aware of this and was sent emails discussing this. On October 27, 2009, Prifitera wrote to Basch, Kraus, and Schild about these plans, and boasted that "Jack and I may be meeting with the owner Mr. Grossman . . ."

146. The practices receiving these valuable free services included Bergen Gastroenterology (at each of its four New Jersey practice sites), Fores Healthcare Associates, Cardiac Associates of New Jersey, Engelwood OB GYN, Endocrinology Associates, P.C., Mendham Medical Group, Pulmonary Associates of North Bergen, Primecare Medical Associates, Somerset OB GYN Associates (two sites), Women's Healthcare of Warren, , Rockland Cardiology, and Diabetes and Endocrinology. All but the last two practices are in New Jersey. The physicians receiving these valuable free services included Alexander Biener, Steven Frier, Joseph Schulman, Deborah Reich-Sobel, Jeffrey Mitchel, Amin Deepak, M.D., and Bonnie Levine, M.D.,

147. Finally, Shiel also provided other incentives to doctors and practices to induce them to use Shiel's lab services. Shiel would provide expensive tickets to Broadway shows or sporting events, lavish dinners and wine and even provide holiday parties and dinners for

provider and provider groups who were large utilizers of Shiel's lab services. For example, Shiel spent an average of $14,785 per year in incentives such as entertainment for Bergen Gastro. In addition, Dr. Howard Hertz received almost $4000 per year in entertainment related perks from Shiel between 2011-2014. These were both providers who also generated a large amount of revenue for Shiel over the same time period.

148. The relationship between this lavish entertainment and Shiel's gains from Medicare billing is stark. From 2010-2014 Shiel spent at least $59,139.49 on the doctors of Bergen Gastroenterology. That generosity was returned, for Shiel's Medicare earnings from Bergen Gastroenterology were $215,013 in 2009, $242008 in 2010, $326,879 in 2011, $472,110 in 2012, and $648,595 in 2013.

149. From 2012-2015 Shiel spent $31,652 entertaining the doctors of Park Medical. In return the Park Medical doctors ordered Shiel lab tests that cost Medicare $295,925 in 2009, $311,283 in 2010, $320,970 in 2011, $367,989 in 2012, and $411,628 in 2013.

150. In 2013 alone the two-doctor office of Hyon & Licciardone received $11,022 in gifts, meals, and entertainment. The doctors ordered so many lab tests that Shiel earned from Medicare, $181,630 in 2009, $206,564 in 2010, $218,079 in 2011, $282,389 in 2012, and $233,885 in 2013.

151. Other well cared for doctors included Howard Hertz, .M.D., who received $11,960.52 2011-2013, Amir Ragadi, M.D., who received $8,850 2012-2105, and Rubino OB GYN, which received $14,215 2011-2014.

D. Shiel Has Given Illegal Financial Inducements to Nursing Homes in Exchange for Referrals

152. When and administrator at a nursing home which gave its clinical laboratory work to Shiel opened an insurance agency as a side business, the administrator asked for and received Shiel's Workers' Compensation insurance account.

153. Shiel also spends thousands of dollars every year on gifts of expensive consumer electronics for its favored skilled nursing facility accounts.

154. Shiel negotiated contracts with nursing homes that offered them large discounts on the SNFs' Medicare Part A labs in exchange for exclusive agreements that gave Shiel all of the SNFs' Part B business.

155. The following nursing homes received discounts on their Part A lab services in exchange for granting Shiel an exclusive agreement for all the SNF's Part B business: Brooklyn United Methodist Church Home (BUMCH), Bushwick Center for Rehabilitation andHealth Care, Concord Nursing Center, Inc. (CNC), Croton Bethel NH, Ditmas ParkRehabilitation, Inc., Dry Harbor Nursing Home, Inc., Fieldston Lodge Nursing Home, Inc., Friedwald Center, Inc., Friedwald Center for Rehabilitation and Nursing, Grandell Rehabilitation and Nursing Center, Inc., Haym Solomon Nursing Home, Inc., Holliswood Care Center, Marcus Garvey Nursing Home, Inc., New East Side Nursing Home, LLC, New Rochelle Nursing Home, Northern Manor Nursing Home, Inc., Northern Riverview Nursing Home, Inc., Oak Hollow Nursing Center (OHNC), Ossining Bethel NH, Queens Nassau Nursing Home, Inc., Ramapo Manor Center for Rehabilitation and Nursing, Ruby Weston Manor, Inc., The Silvercrest Center for Nursing & Rehabilitation, Sutton Park Center for Nursing & Rehabilitation, LLC, Verrazano Nursing Home, Inc.,, Woodbury Center forHealthcare (WCHC), and Woodcrest Nursing Home, Inc. Relator

knows this as henegotiated and received signed contracts from these SNFs that specified discounts on Part A labs in exchange for an exclusive arrangement for their Part B business.

156. Upon information and belief, the nursing homes listed below also received discounts on their Part A lab services in exchange for granting Shiel an exclusive agreement for all of the SNF's Part B business. Alliance Health Associates, Inc (d/b/a Linden Gardens Rehabilitation and Nursing Center), Apex Rehabilitation, Atrium at Park Ridge d/b/a Plaza Regency Care Center (Park Ridge), Belair Care Center, Inc., Berkshire Nursing and Rehabilitation Center, Beth Abraham Health Services, Bishop Charles Waldo MacLean, Inc. (BCWM), Bishop Henry B. Hucles Nursing Home, Cabrini Center for Nursing & Rehabilitation, Cabrini of Westchester for its St. Cabrini Nursing Home, Center for Nursing & Rehabilitation, Cobble Hill Health Center, Inc., Cobble Hill Health Center, Long Term Health Care Program (LTHHCP), Crest Hall Nursing, East Rockaway Care Center, FieldstonLodge, Flushing Manor Care Center, Inc., Hudson Point at Riverdale, Inc., Huntington Hills Nursing Home, Komanoff Center for Geriatric & Rehab Medicine, KZ Corp d/b/a Atrium at Wayne Care Center (Atrium), Lawrence Nursing Care Center, Inc., New Sea Crest Health Care Center, Northern Riverview Nursing Home, Inc., PALJR, LLC d/b/a East Neck Nursing& Rehabilitation Center, Palm Gardens Center (PGC), Pelham Parkway Nursing Care & Rehabilitation Facility, Port Jefferson Healthcare Facility, Rockville, Sans Souchi Rehabilitation and Nursing Center (SSRNC), Shoreview, South Shore Rehabilitation and Nursing Center (SSRN), St. Patrick's Home for the Aged and Infirm, The Riverside, and Wayneview Corp d/b/a Wayneview Care Center. Relator knows this as henegotiated contracts with these SNFs that specified discounts on Part A labs in exchange for an exclusive arrangement for Shiel to handle their Part B business.

157. Offering these discounts to the nursing homes was very profitable for Shiel, as for most nursing homes only 15-20% of the lab tests for Medicare patients were billable under Part A, with the remaining 80-85% of their lab tests falling under Part B of Medicare.

158. Relator had personal knowledge of these illegal inducements at thetime the original and the first amended complaint were filed because Relator was responsible for getting the nursing home contracts signed, including the Part A discounts in exchange for exclusivity, including Part B. This dated back to the mid-1990's. When Relator began this work at Shiel he had been told that discounts were in exchange for exclusivity were a standard business practice. As he gained more experience in the industry, he heard that other laboratories similarly offered pricingarrangements, confirming his mistaken belief that this was a standard industry practice and thatnothing was wrong with it. When Relator filed the original and first amended complaint, he had not focused on the illegality of these contract provisions, because it had been brought up by only one nursing home in nineteen years and the fact that they were another form of kickback. Therefore, these allegations were not originally included in the complaint.

159. When Relator began at Shiel, he was responsible for about 20 nursing home contracts; this number grew to about 100 over the time Relator was employed there. All nursing homes were offered discounts on Part A work in exchange for Shiel being the exclusive lab services provider for that SNF's Part B patients. In the contractsShiel was listed as the "primary provider of laboratory services". This was understood by bothShiel and the nursing home to mean that Shiel was to be to be the ***only*** provider of lab servicesfor the nursing home. All nursing homes wanted at least a 30% discount; most of them receivedthis and Shiel's contracts with the nursing homes included this discount. After execution of a contract, all lab services for the contracted nursing home were provided exclusively by Shiel.

160. Jack Basch and Moshe Kraus required Relator to bring all contractsto them to approve the final discounts. For some nursing homes, Basch would tell Relator what discounts to offer; for others Basch would modify and approve the contract afterRelator relayed to him what discount the nursing home wanted. Further discounts were often given at Jack Basch's or

Moshe Krause's discretion when the nursing homes were billed for lab services for their Part A patients.

161. Many of the nursing homes received additional discounts above and beyond the contracted discount. One nursing home, Brooklyn United, got an additional discount over and above the 30%. Another, Friedwald Center, got a 40% discount on its part A work in exchange for exclusivity for Shiel for part B labs. This was accomplished by combining the 30% discount in the contract with an additional 10% taken off when Shiel billed for part A work. Similarly, further discounts above the 30% base discount that was detailed in the contracts were offered to about 40% of Shiel's nursing home clients. These clients were knownas "Jack's (Basch) clan". Nursing homes that fell into this category included, *inter alia*, Bridgeview, Midway, Fulton Commons, Mayfair, Silverlake, Cliffside, National Healthcare nursing homes, Huntington Hills, Atrium and Ross Healthcare nursing homes (all located in theState of New York). These further discounts were given twice a year when the nursing home would receive its part A bill from Shiel.

162. Upon information and belief, about 25% of nursing homes never paid their Part A bills at all. When Shiel billed them for lab services for their Part A patients, despite the factthat they were already receiving a significant discount on their Part A bill, these nursing homessimply would not pay at all. Shiel did not undertake serious collection activities. For these nursing homes the effective billing rate was $0.00 for each lab test.

163. For example, Silverlake nursing home and Verrazano nursing home, both owned by Otto Weingarten, never paid their Part A bills. When Shiel billed these homes for Part A labs, they did not pay their bill at all, and laughed when Shiel called to request payment.Shiel did not push back or insist upon payment from Silverlake or Verrazano, as Weingarten'snursing homes were a significant source of Part B business for Shiel.

164. These Part A discounts were substantial inducements to the nursing homes. On average, nursing homes were billed about $50,000 to $60,000 per year for labs for Part A

patients. Therefore, the discounts Shiel offered could generate at least $18,000 per year in savings to the nursing homes. For the homes receiving 100% discounts the savings were far higher.

165. These discounts also gave the nursing homes that were receiving these kickbacks the opportunity to pay prices for lab test that were lower than those permitted by the New York Medicaid. Therefore, the kickbacks were not only illegal inducements, but also contravened NY Medicaid fee schedules, which had "best price" requirements that Medicaidpay no more than the lowest amount paid by any other payor.

166. For example, commonly performed and therefore high-volume tests such as the comprehensive metabolic panel (CMP), basic metabolic panel (BMP), and Prothrombin time (Protime) fell below the Medicaid price when offered at discounts between 15% and 35% (depending on year). See attached Exhibits A1-A12.

167. In addition, less frequently performed, but more expensive tests such as those for Vitamin D and Ferritin fell below the Medicaid price when offered at discounts up to 30%. See attached Exhibits A1-A12.

168. Because almost all nursing homes received at least a 30% discount on their Part A labs, this resulted in "best price" violations for almost every SNF for whom Shiel offered this inducement.

169. For nursing homes such as Silverlake and Verrazano, which never paid any Part A bills, there was 100% discount on all lab tests, making any test performed for these homes a violation of NY State lab payment regulations.

170. In addition to the discounts on Part A work, Shiel also offered other inducements to nursing homes to secure exclusive arrangements to do all Part B labs. For example, Shiel did not charge the nursing homes for any labs done for patients covered by an

HMO. For example, one Blue Cross HMO paid the nursing home an all-inclusive per diem rate which included all laboratory services. By not charging the nursing homes for these labs,Shiel allowed the nursing homes to keep more of the per diem rate paid by the HMO for theirown profit.

171. Furthermore, all nursing homes owned by the ownership of Klein and Rubin including *inter-alia* Hopkins Care Center, Oceanside Care Center, Park Terrace, Grandel Care Center, Beach Terrace and Queens Nassau were not charged Part A travel fees for venipuncture (i.e., the travel costs a phlebotomist would incur when traveling to a nursing home to take a patient's blood. This travel fee is a cost that would have come out of the per diem rate paid to the nursing home by Part A. By not charging a nursing home for the travel fee, Shiel allowed the nursing home to keep more of the per diem rate paid by Medicare Part A for its own profit.

172. Silverlake nursing home in NY, received further inducements. A blood gas machine was placed in a broom closet and was deemed a "lab" by Shiel. Shiel paid a monthly fee to Silverlake for this onsite "lab" and stated that Shiel's medical director, Dr. Romano was also medical director of this "lab". Shiel also paid a monthly fee to Silverlake for a respiratory therapist, Elliot Spira, even though Spira was a Silverlake employee. In addition, Shiel paid a monthly fee to Silverlake's medical director. These bogus arrangements provided additional incentive for Silverlake to give Shiel exclusivity for its Part B work. Shiel was particularly motivated to offer incentives to Silverlake, as over 70% of its lab work was covered under PartB.

173. Cliffside nursing home in NY had a similar arrangement with Shiel, where Shiel provided payments to the nursing home for a bogus lab. Shiel was particularly motivatedto offer this incentive to Cliffside, as Cliffside also had a large proportion of Part B business.

E. Defendants Knew That These Financial Inducements Were Illegal

174. Defendants knew that compliance with the Stark Law and Anti-Kickback Statute was a condition of payment by Medicare. Defendants explicitly certified that, as a Medicare supplier, they would comply with all Medicare laws and regulations, including the Stark Law and Anti-Kickback Statute, on Form CMS-855B and CMS-1500 claims forms.

175. Defendants knowingly compensated physicians and skilled nursing facilities in exchange for referrals, in violation of the Stark Law and Anti-Kickback Statute. Defendants paid kickbacks and dispensed gifts expressly to obtain referrals, to increase the number of tests referred, and to prevent customers from affiliating with competitors. These kickbacks were expressly approved by top level Shiel and Fresenius management, in particular Jack Basch.

176. At least one Shiel account representative would purchase gifts for customers and was told to manufacture receipts that "make sense". With company approval, he would turn in fake invoices for repair work or would turn in receipts for expensive personal items thatappear to be business-related and would cover the costs of the gifts he had been directed to purchase, thus concealing the inducement in the event of an audit or investigation.

V. THE UNITED STATES AND THE STATES OF NEW YORK AND NEW JERSEY WERE HARMED BY DEFENDANTS' CONDUCT

177. As a result of Defendants' conduct, the Medicare program paid Defendants tens of millions of dollars for false and/or fraudulent claims for laboratory tests.

178. Medicare was directly affected by Defendants' fraudulent schemes. Estimates of Medicare / Medicaid, or Proxy Estimates of SNF residents.

179. Medicare was particularly susceptible to Defendants' fraudulent schemes because it does not require a patient co-payment on laboratory services. Because Medicare

patients were not required to pay out-of-pocket for laboratory services, they had no reason to inquire into the charges to Medicare associated with them.

180. The damages to the United States and the States of New York and New Jersey arising from the Defendants' submission of claims to Medicare and Medicaid referred by these physicians in violation of Stark Law is also in the millions of dollars.

181. The damages to the United States and the States of New York and New Jersey arising from the Defendants' submission of claims to Medicare and Medicaid for laboratory teststhat were not reasonable and necessary for the diagnosis or treatment of patients, and for whichthe need was not assessed or documented for individual patients, including the claims referencedin Section IV, E above, likely exceeds tens of millions of dollars.

COUNT I

(Federal False Claims Act: Presentation of False Claims)

(31 U.S.C. § 3729(a)(1) and (a)(1)(A))

182. Relator repeats and reloads and hereby incorporates by reference paragraphs1 through 181 inclusive set out above as though fully set forth herein.

183. Defendants knowingly presented, or caused to be presented, false and fraudulent claims for payment or approval to the United States and New York and New Jersey Medicaid, including those claims for reimbursement of laboratory drug tests that violated the Stark Law and the Anti-Kickback Statute and that were ordered by physicians for uses that were not reasonable and necessary for the diagnosis or treatment of individual patients.

184. Said claims were presented with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

COUNT II

(Federal False Claims Act: False Statements Material to False Claims) (31 U.S.C. § 3729(a)(1)(B))

185. Relator repeats and reloads and hereby incorporates by reference paragraphs1 through 181inclusive set out above as though fully set forth herein.

186. Defendants knowingly made, used, and caused to be made or used, false records or statements — i.e., false statements regarding compliance and coverage for its services and false statements on forms CMS-855B, 837P and CMS-1500—to get false or fraudulent claims paid and approved by the United States.

187. Defendant's false certifications and representations were made to get claims paid even though there was no evidence of medical reasonableness or medical necessity, and payment of the false or fraudulent claims was a reasonable and foreseeable consequence of the Defendant's statements and actions.

188. The false certifications and representations made and caused to be made by Defendant were material to the United States' and New York and New Jersey Medicaid's payment of the false claims.

189. Said false records or statements were made with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

COUNT III

FAILURE TO RETURN OVERPAYMENTS FALSE CLAIM

(Federal False Claims Act; 31 U.S.C. § 3729(b)(e)

190. Relator repeats and reloads and hereby incorporates by reference paragraphs1 through 181inclusive set out above as though fully set forth herein.

191. Defendants were each put on notice of potential of potential overpayments. Shiel, BIM, and Basch knew that some account representatives had forged doctor's signatures, some had inserted ICD9/10 codes on their own and knew that these requisition slips falsely purporting to represent a physician's authorization were the condition precedent to claims being submitted to Medicare and Medicaid. Shiel, BIM, and Basch also knew that Shiel had offered incentives to doctors to attract and maintain their business. The incentives included expensive subsidies for EMR set-up and installation as well as subsidized monthly fees and general-purpose hardware and were available only to medical practices that generated enough profitable laboratory business for Shiel/BIM. The incentive payments were continued for years, establishing and maintaining financial relationships between the doctors and Shiel. Shiel, BIM, and Basch also knew that doctors and medical staff had received tickets to expensive entertainment and sporting events and expensive meals and parties. Finally, Shiel, BIM, and Basch knew especially lucrative practices were being aided by Shiel-hired and paid for phlebotomists. Each of these factors at a minimum posed a compliance risk, yet neither Shiel, BIM, or Jack Basch cared to look further lest they discover potential liability to refund overpayments, with its attendant obligations.

192. Spectra and Fresenius were also on notice of potential overpayments. While Fresenius was evaluating whether to buy Shiel, Shiel, at Basch's direction, had made representations about its revenue stream. Between the changes wrought by the acquisition and the much more fraud- resistant disease coding standards when ICD10 finally came on line, there was an immediate and material decrease in bill submissions, and a concomitant loss of reimbursement. Vice President of Compliance and Billing, Gitty Kohn, had maintained her position through the acquisition and was in very frequent contact with Phil Hayden and Barry Schwartz, who were respectively the Vice President of Finance and the Senior Director of Reimbursement. Kohn's frequent contact with them gave her a bird's eye view of what they were thinking as they watched

Shiel's revenue plummet. Kohn both participated in discussions with them and overheard their conversations and repeatedly affirmed to Relator and others that they knew what was going on, both with respect to the falling revenue and its cause – Shiel's inability to continue to maintain a high level of false diagnostic coding. Hayden and Schwartz knew there was a serious potential of overpayments long before the Department of Justice served its Civil Investigative Demand toward the end of 2016. That demand, and the subsequent interview of the Relator should have turned that worry about potential overpayments into a virtual certainty. Despite this, Realtor asserts, upon information and belief that no serious and searching audit was conducted, and either no money or the smallest fraction of the actual overpayments, was refunded.

193. Defendants have nonetheless refused to conduct audits that are within them power to conduct in the full knowledge that those audits would reveal the precise amount of overpayment refunds due Medicare because each of the previously enumerated false billing schemes.

194. Defendants' refusal to calculate or estimate the amount of overpayment refunds owed is a separate violation of 31 U.S.C. §3729(b)(3) of the False Claims Act.

COUNT IV

VIOLATION OF THE NEW YORK FALSE CLAIMS ACT

(NEW YORK STATE FINANCE LAW, - ARTICLE XIII §§ 187 *et seq.*)

195. Relator repeats and reloads and hereby incorporates by reference paragraphs1 through 181inclusive set out above as though fully set forth herein.

196. The New York Medicaid Provider Enrollment Application requires a certification that the provider agrees to "abide by all applicable Federal and State laws as well as the rules and regulations of other New York State agencies peculiar to the type of program covered by this enrollment application."

197. The New York False Claims Act (NY State Finance Law, Ch. 56 of the Consolidated Laws - Article XIII §§187 *et seq*.) provides in pertinent part as follows:

> §189. Liability for certain acts.
>
> 1. Subject to the provisions of subdivision two of this section, any person who:
>
> (a) knowingly presents, or causes to be presented, to any employee, officer or agent of the state or a local government, a false or fraudulent claim for payment or approval;
>
> (b) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> ***
>
> (g) knowingly makes, uses or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state or local government;
>
> shall be liable to the states or a local government as applicable, for a civil penalty of not less than six thousand dollars and not more than twelve thousand dollars, plus three times the amount of all damages, including consequential damages, which the state or local government sustains because of the act of that person.

198. Pursuant to Section 188(3) of the New York False Claims Act, proof of specific intent to defraud is not required.

199. As set forth herein, Defendant has violated the New York False Claims Act in New York State Finance Law Ch.56, Article XIII §§ 189(1)(a), 189(1)(b), 189(1)(c), and 189(1)(g).

200. As explained in detail Defendants have submitted false claims and/or false records for laboratory tests for which there was no evidence of medical necessity or medical reasonableness, or which were procure through the use of illegal financial inducements; or both.

201. As also explained in detail, Defendants have refused to calculate or repay overpayments despite knowledge that they have received substantial overpayments.

202. The Defendants knowingly violated N.Y. State Fin. Law § 189 and knowingly presented or caused to be made, used and presented hundreds of thousands of false claims to the State of New York from 2008 to the present, by violating the Federal Anti-Kickback Act,as described herein.

203. The State of New York, by and through the State of New York Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

204. Given the structure of the health care systems, the false claims, statements, representations, material omissions, and/or records made by the Defendants had the potentialto influence the State of New York's payment decision.

205. As a result of the Defendants' violations of N.Y. State Fin. Law § 189, the State of New York has been damaged.

206. For each violation of the New York False Claims Act, New York is entitled to recover treble damages from Defendant. *See* New York False Claims Act§189 (h).

207. In addition, for each violation of the New York False Claims Act, New York is entitled to recover from Defendant a civil penalty of not less than $6000, and not more than $12,000. *Id.*

208. There are no bars to recovery under N.Y. State Fin. Law. § 190(9), and, or in the alternative, Relator is an original source as defined therein. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.Y. State Fin. Law § 190(2) on behalf of himself and the State of New York.

209. To the extent that any allegations or transactions herein have been publicly disclosed, Relator has knowledge that is independent of and materially adds to any publicly disclosed allegationsor transactions. Contemporaneously with filing, Relator has provided all material documents related to this Complaint to the Attorney General of the State of New York. This Complaint details Relator's discovery and investigation of Defendants' fraudulent schemes and is supported by documentary evidence.

COUNT V

VIOLATION OF THE NEW JERSEY FALSE CLAIMS ACT

210. Relator repeats and reloads and hereby incorporates by reference paragraphs1 through 181 inclusive set out above as though fully set forth herein.

211. The New Jersey Medicaid Provider Enrollment Application requires a certification that the provider agrees "to comply with all applicable State and Federal Medicaid laws and policies, and rules and regulations promulgated pursuant thereto " and agrees "to comply with Section 1909 of P.L. 92-603, Section 242© which makes it a crime for persons found guilty of making any false statement or representation of a material fact in order to receiveany benefit or payment under the Medicaid Assistance program…." Provider Agreement Between New Jersey Department of Health and Senior Service and Provider, at 1, Items 1 and 5.

> § 2A:32C-3 of the New Jersey Statutes provides liability for any person who-
>
> (a) knowingly presents or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;

> (b) knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State;
>
> (c) conspires to defraud the State by getting a false or fraudulent claim allowed or paid by the State.
>
> . . .
>
> (g) Knowingly makes, uses, or causes to be made or used orto be used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.
>
> Pursuant to §2A:32C-2 proof of specific intent to defraud is not required.

213. As explained in detail Defendants have submitted false claims and/or false records for laboratory tests for which there was no evidence of medical necessity or medical reasonableness, or which were procure through the use of illegal financial inducements; or both.

214. As also explained in detail, Defendants have refused to calculate or repay overpayments despite knowledge that they have received substantial overpayments.

215. The Defendants knowingly violated N.J. Stat. Ann. § 2A:32C-3 and knowingly presented false claims to the State of New Jersey from 2009 to the present, by violating the Federal Anti-Kickback Act, as described herein.

216. The State of New Jersey, by and through the State of New Jersey Medicaid program and other state health care programs, paid the false and/or fraudulentclaims.

217. Given the structure of the health care systems, the false claims, statements, representations, material omissions, and/or records made by the Defendants had the potentialto influence the State of New Jersey's payment decision.

218. As a result of the Defendants' violations of N.J. Stat. Ann. § 2A:32C-3189,the State of New Jersey has been damaged.

219. For each violation of the New Jersey False Claims Act, New Jersey is entitled to recover treble damages from Defendant under the New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32-C1–2A:32-C18.

220. In addition, for each violation of the New Jersey False Claims Act, New Jersey is entitled to recover from Defendant a civil penalty of not less than $5,500, and not more than $11,000. *Id.*

221. There are no bars to recovery under N.J. Stat. Ann. § 2A:32C-9(c), and, or in the alternative, Relator is an original source as defined therein. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.J. Stat. Ann. § 2A:32C-5(b) on behalf of himself and the State of New Jersey. To the extent that any allegations or transactions herein have been publicly disclosed, Relator has knowledge that is independent of and materially adds to any publicly disclosed allegations or transactions. Contemporaneously with filing, Relator has provided all material documents related to this Complaint to the Attorney General of the State of New Jersey.

COUNT VI

(For James Gordon, and Against Fresenius Medical Care Holdings and Spectra Holdco Only)

ILLEGAL RETALIATION IN VIOLATION OF

THE FEDERAL FALSE CLAIMS ACT

222. Gordon repeats and repleads each and every one of the allegations in Paragraphs 1 through 181, inclusive, as though fully set forth herein.

223. Defendant Shiel moved its primary place of business to New Jersey. Since its sale to Fresenius, the laboratory business has been operated by Spectra Laboratories, in Rockleigh, New Jersey.

224. James Gordon formed the corporate entity which was denominated as the Relator in this action. At all times material hereto, Gordon was employed first by Shiel, then by BIM, and then bySpectra which is owned and controlled by Fresenius.

225. Defendants knew that there was a distinct possibility that Gordon might becomea whistle blower.

226. Gordon made his dissatisfaction with Defendants' illegal conduct well known throughout the company both before and after Fresenius bought it. He made numerous complaints to the compliance officer, repeatedlyvoicing his concern that fabricating and submitting diagnostic codes was illegal and tantamount to Medicare fraud.

227. Gordon also warned many of his sales colleagues that submitting codes was illegal and would get them and the company into trouble.

228. Gordon also inadvertently used a company email account to forward an email to one of his lawyers, whose email address is mkleiman@quitam.org.

229. Since Fresenius has been a defendant in numerous *qui tam* cases and has paid hundreds of millions of dollars to the United States to settle allegations that it has committed Medicare fraud and Medicaid fraud, it is well aware that "qui tam" refers to a type of lawsuit brought by a whistle blower in the name of the United States.

230. Finally, as the Court is aware, in November or December of 2016, the United States served a Civil Investigative Demand on Fresenius, and in January 2017, Fresenius was made aware ofthe fact that a False Claims Act complaint had been filed against it. Fresenius ordered Gordon to submit to an interview by Fresenius' counsel. At that interview Gordon described the pressure that he and the other account representatives were placed under to cause the submission of claims that had diagnostic codes that had no known relationship to the patients' medical conditions, and were merely the guesses of the untrained representatives. Gordon also described the numerous financial inducements and related miscondiuct described above.

231. On February 21, 2017, within a month of Fresenius receiving this information, Gordon was fired while taking two of his children on a college tour.

232. In doing the things hereinabove alleged, Defendants Fresenius Medical Care; Fresenius Medical Care Holdings, Inc.; Spectra Holdco, LLC; and Doe 3, inclusive, violated 31 U.S.C.§3730(h).

233. As a direct legal consequence of his wrongful firing, Gordon has lost, and shall continue to lose income, commissions, bonuses, and other valuable benefits in an amount uncertain as of this moment, but to be plead and proven at trial.

234. As a consequence of his wrongful firing, Gordon has suffered and shall continue to suffer anxiety and emotional distress in an amount uncertain as of this moment, but to be plead and proven at trial.

235. As a consequence of his wrongful firing, Gordon has incurred and shall continue to incur legal fees and costs in an amount uncertain as of this moment, but to be plead and proven at trial.

COUNT VII

((For James Gordon, and Against Fresenius Medical Care Holdings and Spectra Holdco Only)

ILLEGAL RETALIATION IN VIOLATION OF

THE NEW JERSEY CONSCIENTIOUS EMPLOYEE PROTECTION ACT

236. Gordon repeats and repleads each and every one of the allegations in Paragraphs1 through 181, inclusive set out above, as though fully set forth herein.

237. In raising these complaints and issuing these warnings, Gordon had an objectively reasonable and good faith belief that the conduct he was decrying violated the federal False Claims Act and various state statutes, as enumerated *supra*.

238. In doing the things hereinabove alleged, Defendants Fresenius Medical Care; Fresenius Medical Care Holdings, Inc.; Spectra Holdco, LLC; and Doe 3, inclusive, violated N.J.S.A. 34:19- 1, *et. seq.* 31 U.S.C. §3730(h), directly and legally causing damage to Doe as hereinabove alleged.

PRAYER FOR RELIEF

Counts I through V

WHEREFORE, the Relator demands and prays that judgment be entered in favor of the United States and the States of New York and New Jersey in against Defendants as follows:

1. For the amount of the damages to the United States or the State of New York or the State of New Jersey, trebled as required by law, and such civil penalties as are authorized by law, together with all such further relief as may be just and proper;

2. For the Relator, the maximum amount of the Relator's share allowed by law;

3. Reimbursement for all reasonable expenses that Relator incurred in connection with this action;

4. An award of reasonable attorneys' fees and costs; and

5. Such further relief as this Court deems just and proper.

Count VI

WHEREFORE, Relator, James Gordon, demands and prays that judgment be entered in his favor against Defendants Shiel Medical Laboratory; Shiel Holdings, LLC; Fresenius Medical Care; Fresenius Medical Care Holdings, Inc.; Spectra Holdco, LLC; and Doe 3, inclusive, as follows:

6. For two times Gordon's lost earnings and benefits;

7. For all future lost earnings and benefits;

8. For an amount sufficient to compensate Gordon for his pain, suffering,and emotional distress;

9. Reimbursement for all reasonable expenses, including, *inter alia,* attorney's fees, that Gordon incurred in connection with this action; and

10. Such further relief as this Comi deems just and proper.

Count VII

WHEREFORE, Relator James Gordon demands and prays thatjudgment be entered in his favor against Defendants Shiel Medical Laboratory; Shiel Holdings, LLC; Fresenius Medical Care; Fresenius Medical Care Holdings, Inc.; Spectra Holdco, LLC; and Doe 3, inclusive, as follows:

11. For Gordon's lost earnings and benefits;

12. For all future lost earnings and benefits;

13. For an amount sufficient to compensate Gordon for his pain, suffering, and emotional distress;

14. For punitive or exemplary damages in an amount sufficient to punish the Defendants and to deter future similar misconduct;

15. Reimbursement for all reasonable expenses, including, *inter alia,* attorney's fees, that Gordon incurred in connection with this action; and

16. Such further relief as this Court deems just and proper.

Respectfully submitted,

/s/s Steven J. Marcus

Dated: 11/16/23

S teven J. Marcus
NY Bar No. 1231307
431 W. 22nd Street
New York, NY 10011
212-989-6187
Sjmarcus3@aol.com

Dated: 11/16/23

KLEIMAN / RAJARAM

Mark Allen Kleiman (CSB #115919)
(pro hac vice)
Pooja Rajararm (CSB #241777)
(pro hac vice)
12121 Wilshire Boulevard
Suite 810
310-392-5455
310-306-8491 (fax)
mkleiman@quitam.org
prajaram@quitam.org

Dated: 11/16/23

HALLORAN SAGE, LLP

//s/ Howard L. Pierce

Howard L. Pierce
Fed. Bar No. HP5655
One Goodwin Square
225 Asylum Street
Hartford, CT 06103
Telephone: 860-297-4655
Fax:(860) 548-000
pierceh@halloransage.com

Dated: 11/16/23

/s/s Morris R. Borea

Morris R. Borea
Fed Bar No. ct06559
Halloran & Sage LLP
One Goodwin Square
225 Asylum Street
Hartford, Connecticut 06103
Phone: 860.297.4676
Fax: 860.548.0006
borea@halloransage.com

DEMAND FOR JURY TRIAL

The Relator demands a jury trial in this case.

Respectfully submitted,

Dated: 11/16/23

/s/ Steven J. Marcus

Steven J. Marcus
NY Bar No. 1231307
431 W. 22nd Street
New York, NY 10011
212-989-6187
Sjmarcus3@aol.com

Dated: 11/16/23

KLEIMAN / RAJARAM

Mark Allen Kleiman (CSB #115919)
(pro hac vice)
Pooja Rajararm (CSB #241777)
(pro hac vice)
12121 Wilshire Boulevard
Suite 810
Los Angeles CA 90025
310-392-5455
310-306-8491 (fax)
mkleiman@quitam.org
prajaram@quitam.org

Dated: 11/16/23

HALLORAN & SAGE, LLP

/s/ Howard L. Pierce

Howard L. Pierce
Fed. Bar No. HP5655
One Goodwin Square
225 Asylum Street
Hartford, CT 06103
Telephone: 860-297-4655
Fax:(860) 548-000
pierceh@halloransage.com

Dated: 11/16/23

/s/ Morris R. Borea

Morris R. Borea
Fed Bar No. ct06559
Halloran & Sage LLP
One Goodwin Square
225 Asylum Street
Hartford, Connecticut 06103
Phone: 860.297.4676
Fax: 860.548.0006
borea@halloransage.com

EXHIBIT A1

2009

Test	Medicare	Medicaid	% Discount	Amount Below Medicaid
CMP				
80053	$13.96	$10.00	30%	$0.23
BM				
80048	$9.33	$7.25	25%	$0.25
80047 (w/ion)	$9.33	$7.25	25%	$0.25
Prothrombin/Protime				
85610	$5.74	$3.91	35%	$0.18
Vitamin D				
82306	$43.22	$36.60	20%	$2.02
Ferritin				
82728	$19.89	$14.75	30%	$0.83

EXHIBIT A2

2010

Test	Medicare	Medicaid	% Discount	Amount Below Medicaid
CMP				
80053	$13.69	$10.00	30%	$0.42
BM				
80048	$9.15	$7.25	25%	$0.39
80047 (w/ion)	$9.15	$7.25	25%	$0.39
Prothrombin/Protime				
85610	$5.62	$3.91	35%	$0.26
Vitamin D				
82306	$42.40	$36.60	15%	$0.56
Ferritin				
82728	$19.51	$14.75	25%	$0.12

EXHIBIT A3

2011

Test	Medicare	Medicaid	% Discount	Amount Below Medicaid
CMP				
80053	$13.45	$10.00	30%	$0.59
BMP				
80048	$8.99	$7.25	20%	$0.06
80047 (w/ion)	$8.99	$7.25	20%	$0.06
Prothrombin/Protime				
85610	$5.53	$3.91	30%	$0.04
Vitamin D				
82306	$41.66	$36.60	15%	$1.19
Ferritin				
82728	$19.17	$14.75	25%	$0.37

EXHIBIT A4

2012

Test	Medicare	Medicaid	% Discount	Amount Below Medicaid
CMP				
80053	$13.54	$10.00	30%	$0.52
BMP				
80048	$9.05	$7.25	20%	$0.01
80047 (w/ion)	$9.05	$7.25	20%	$0.01
Prothrombin/Protime				
85610	$5.56	$3.91	30%	$0.02
Vitamin D				
82306	$41.94	$36.60	15%	$0.95
Ferritin				
82728	$19.30	$14.75	25%	$0.28

EXHIBIT A5

2013

Test	Medicare	Medicaid	% Discount	Amount Below Medicaid
CMP				
80053	$13.14	$10.00	25%	$0.15
BMP				
80048	$8.78	$7.25	20%	$0.23
80047 (w/ion)	$8.78	$7.25	20%	$0.23
Prothrombin/Protime				
85610	$5.40	$3.91	30%	$0.13
Vitamin D				
82306	$40.70	$36.60	15%	$2.01
Ferritin				
82728	$18.73	$14.75	25%	$0.70

EXHIBIT A6

2014

Test	Medicare	Medicaid	% Discount	Amount Below Medicaid
CMP				
80053	$13.04	$10.00	25%	$0.22
BMP				
80048	$8.71	$7.25	20%	$0.28
80047 (w/ion)	$8.71	$7.25	20%	$0.28
Prothrombin/Protime				
85610	$5.37	$3.91	30%	$0.15
Vitamin D				
82306	$40.40	$36.60	10%	$0.24
Ferritin				
82728	$18.59	$14.75	25%	$0.81

EXHIBIT A7

2015

Test	Medicare	Medicaid	% discount	Amount Below Medicaid
CMP				
80053	$13.01	$10.00	25%	$0.24
BMP				
80048	$8.69	$7.25	20%	$0.30
80047 (w/ion)	$8.69	$7.25	20%	$0.30
Prothrombin/Protime				
85610	$5.35	$3.91	30%	$0.17
Vitamin D				
82306	$40.29	$36.60	10%	$0.34
Ferritin				
82728	$18.54	$14.75	20%	$0.08

EXHIBIT A8

Lab test	Medicare Fee Schedule--2016	NYS Medicaid Fee schedule--2016	Percent discount offered by Shiel at which Medicare price falls below Medicaid price	Amount below Medicaid price
CMP	$13.02	$10	25%	$.23
BMP	$8.70	$7.25	20%	$.29
Prothrombin/Protime	$5.36	$3.91	30%	$.16
Vitamin D	$40.33	$36.60	15%	$2.32
Ferritin	$18.57	$14.75	25%	$.82

EXHIBIT A9

Lab test	Medicare Fee Schedule--2017	NYS Medicaid Fee schedule--2017	Percent discount offered by Shiel at which Medicare price falls below Medicaid price	Amount below Medicaid price
CMP	$13.11	$10	25%	$.17
BMP	$8.76	$7.25	20%	$.25
Prothrombin/Protime	$5.39	$3.91	30%	$.14
Vitamin D	$40.61	$36.60	15%	$2.08
Ferritin	$18.70	$14.75	25%	$.72

EXHIBIT A10

Lab test	Medicare Fee Schedule--2018	NYS Medicaid Fee schedule--2018	Percent discount offered by Shiel at which Medicare price falls below Medicaid price	Amount below Medicaid price
CMP	$13.04	$10	25%	$.22
BMP	$10.44 $13.73 (w/ionized Ca)	$7.25	35% 50%	$.48 $.38
Prothrombin/Protime	$4.85	$3.91	20%	$.03
Vitamin D	$36.55	$36.55	Any discount will be below Medicaid rate	$5.48(with 15% discount)
Ferritin	$16.83	$14.75	15%	$.44

EXHIBIT A11

Lab test	Medicare Fee Schedule--2019	NYS Medicaid Fee schedule--2019	Percent discount offered by Shiel at which Medicare price falls below Medicaid price	Amount below Medicaid price
CMP	$11.74	$10	15%	$.02
BMP	$9.40 $13.73 (w/ionized Ca)	$7.25	25% 50%	$.20 $.38
Prothrombin/Protime	$4.37	$3.91	15%	$.20
Vitamin D	$32.89	$36.55	N/A—Medicare rate is below Medicaid (??)	N/A Medicare rate is below Medicaid (??)
Ferritin	$15.15	$14.75	5%	$.36 $1.87 (at 15% discount)

EXHIBIT A12

Summary Table

Discounts at which Medicare price falls below Medicaid:

Year	CMP	BMP	Protime	Vitamin D	Ferritin
2009	30%	25%	35%	20%	30%
2010	30%	25%	35%	15%	25%
2011	30%	20%	30%	15%	25%
2012	30%	20%	30%	15%	25%
2013	25%	20%	30%	15%	25%
2014	25%	20%	30%	10%	25%
2015	25%	20%	30%	10%	20%
2016	25%	20%	30%	15%	25%
2017	25%	20%	30%	15%	25%
2018	25%	35%	20%	Any	15%
2019	15%	25%	15%	****	5%

*** Medicare price was below NYS Medicaid fee schedule price